EXHIBIT M

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16 17 18	SUPERIOR COURT OF NEW JERSEY LAW DIVISION ATLANTIC COUNTY CASE NO. 291 CT MASTER CASE NO. L-6341-10 IN RE: PELVIC MESH/GYNECARE LITIGATION CONFIDENTIAL - ATTORNEYS' EYES ONLY VOLUME II Friday, November 16, 2012 Continued oral deposition of DANIEL STEVEN ELLIOTT, M.D., held at MAZIE SLATER KATZ & FREEMAN, L.L.C., 103 Eisenhower Parkway, Roseland, New Jersey, commencing at approximately 8:25 a.m., before Rosemary Locklear, a Registered Professional Reporter, Certified Realtime Reporter, Certified Court Reporter (NJ License No. 30XI00171000), and Notary Public. GOLKOW TECHNOLOGIES, INC. 877.370.3377 ph 971.591.5672 Fax deps@golkow.com	Page 322	1 AF 2 3 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25	ANDERSON LAW OFFICES, L.L.C. BY: BENJAMIN H. ANDERSON, ESQUIRE ben@andersonlawoffices.net 1360 West 9th Street, Suite 215 Cleveland, Ohio 44113 (216) 589-0256 Appearing on behalf of the Plaintiffs BUTLER SNOW O'MARA STEVENS & CANNADA, P.L.L.C. BY: NILS B. (BURT) SNELL, ESQUIRE burt.snell@butlersnow.com 500 Office Center Drive, Suite 400 Fort Washington, Pennsylvania 19034 (267) 513-1885 Appearing on behalf of the Defendants Johnson & Johnson and Ethicon SILLS CUMMIS EPSTEIN & GROSS, P.C. BY: WILLIAM R. STUART, III., ESQUIRE wstuart@sillscummmis.com The Legal Center, One Riverfront Plaza Newark, New Jersey 07102 (973) 643-7000 Appearing on behalf of the Defendant Caldero Medical, Inc.	Page 323
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	I N D E X WITNESS PAGE DANIEL STEVEN ELLIOTT, M.D. By Mr. Snell 328 EXHIBIT INDEX MAR Elliott 9 11-page copy of article dated 8/10 410 entitled "Vaginal Mesh for Prolapse" 10 9-page copy of article dated 2/11 420 entitled "Trocar-Guided Mesh Compared With Conventional Vaginal Repair in Recurrent Prolapse" (Exhibits retained by the court reporter and attached to transcript.)	Page 324	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25	DEPOSITION SUPPORT INDEX Directions to Witness Not to Answer Page Line Request for Production of Documents Page Line Stipulations Page Line Question Marked Page Line	Page 325

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Reserved for Confidential Designation Index as Pursuant to the Protective Order	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Page 327 Reserved for Confidential Designation Index as Pursuant to the Protective Order
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24 25		24 25	
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25	DANIEL STEVEN ELLIOTT, M.D., having been previously duly sworn, was examined and testified as follows: EXAMINATION (Continued) BY MR. SNELL: Q. Good morning, Doctor. How are you doing this morning? A. Fine. Q. We're going to resume your deposition. Between the end of the deposition yesterday and this morning did you review any materials, any literature, anything like that? A. Just my private notes. Q. I'm sorry. Your what? A. My notes. Q. What notes are these? A. Just notes that I've taken on the depositions. Q. Of the different Ethicon witnesses? A. Correct. Q. Any notes that you've taken on any other witnesses?	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25	A. No. Just Ethicon depositions. Q. So no notes on depositions in the Gross case; correct? A. No. No. I can tell you Gauld or Gauld, Walji, Robinson, Kirkemo, Hinoul. I'll never get that one. MR. ANDERSON: You did great on that. THE WITNESS: There may be another one in there. Those are the ones I've BY MR. SNELL: Q. Do you know Larry Sirls, a urologist? A. I do not believe I've ever met him. He is in our same north central section of the AUA, which incorporates Michigan, so I believe he's in Michigan. So I may have encountered him at a meeting but, again, I don't recall ever meeting him. Q. Have you ever seen him speak or present, that you recall? A. I do not recall. I may have, actually. I don't recall. Q. Do you have any criticisms of him

	•	Page 330		Page 331
1	as a surgeon?	-	1	attend meetings that are going to be
2	A. No. I don't know him as a		2	overlapped. I may have encountered him, but
3	surgeon at all so I but I have no		3	I don't recall ever doing that.
4	criticism.		4	Q. That's what I was going to ask
5	Q. Do you know Elizabeth Kavaler,		5	you.
6	also a urologist?		6	Do you attend the AUGS
7	A. No. To the best of my knowledge,		7	conferences in addition to the urologic
8	I've never met her.		8	conferences that you strike that. That
9	Q. Do you know Miles Murphy,		9	was a bad question.
10	urogynecologist?		10	Do you attend the AUGS
11	A. No.		11	conferences?
12	Q. Never met him or seen him?		12	A. No. I attend primarily urologic
13	A. To the best of my knowledge, no.		13	meetings. However, with that said, the IUGA
14	Q. Any criticisms of Miles Murphy		14	meetings I've attended at times, especially
15	that you have?		15	when they're in concert with the
16	A. Well, I mean, ethically, no,		16	International Continence Society, which I'm
17	surgically, no. I don't agree with some of		17	much more involved in.
18	the conclusions he reached in his papers,		18	Q. What type of urologic conferences
19	but that's limited to that.		19	do you attend regularly, let's say in the
20	Q. Vince Lucente, have you ever met		20	past, since 2001 since you've been back at
21 22	him?		21 22	Mayo following your fellowship?
	A. No.			A. Regularly, the north central
23	Q. Have you ever seen him speak or		23	section of the AUA, which is the American
24 25	present at any conferences?		24	Urologic Association. Then the AUA meeting,
25	A. Not that I know of. But we		25	our national meeting. International
		Daga 222		Daga 222
1	Continence Society. I'd have to look at my	Page 332	1	Page 333 personal experience, I have not encountered
2	because I attend meetings all over.		2	significant problems with it, so relative to
3	There's a number of robotic ones.		3	specifically my personal experience, it
4	Q. Okay.		4	would be fair to say I'm pro-mesh.
5	A. In my CV it has the ones that		5	BY MR. SNELL:
6	were given presentations.		6	Q. And you're pro-mesh for the use
7	Q. Do you have any criticisms of		7	of mesh to treat pelvic organ prolapse as
8	Dr. Vince Lucente?		8	long as it's not transvaginally placed.
9	A. Again, the same as with		9	A. Correct.
10	Dr. Murphy: I don't have any surgical,		10	MR. ANDERSON: Objection.
11	ethical. My conclusions are different than		11	Go ahead.
12	his, but that's on an academic level.		12	THE WITNESS: Correct. From
13	Q. What conclusions do you have at		13	transabdominal, laparoscopic or robotic, I
14	an academic level that are different than		14	am pro-mesh for that.
15	Dr. Lucente's?		15	BY MR. SNELL:
16			16	Q. Yesterday we were talking about
TO	A. On the very proad thing broad			
	A. On the very broad thing broad scale, he is pro-mesh, I am anti-mesh in the			
17	scale, he is pro-mesh, I am anti-mesh in the		17	doing a concomitant hysterectomy with
17 18	scale, he is pro-mesh, I am anti-mesh in the case of pelvic organ prolapse done		17 18	doing a concomitant hysterectomy with sacrocolpopexy.
17 18 19	scale, he is pro-mesh, I am anti-mesh in the case of pelvic organ prolapse done transvaginally.		17 18 19	doing a concomitant hysterectomy with sacrocolpopexy. A. Yes.
17 18 19 20	scale, he is pro-mesh, I am anti-mesh in the case of pelvic organ prolapse done transvaginally. Q. So you're pro-mesh for stress		17 18 19 20	doing a concomitant hysterectomy with sacrocolpopexy.
17 18 19 20 21	scale, he is pro-mesh, I am anti-mesh in the case of pelvic organ prolapse done transvaginally. Q. So you're pro-mesh for stress urinary incontinence; correct?		17 18 19 20 21	doing a concomitant hysterectomy with sacrocolpopexy. A. Yes. Q. Do you recall, in general, that? A. Yes.
17 18 19 20 21 22	scale, he is pro-mesh, I am anti-mesh in the case of pelvic organ prolapse done transvaginally. Q. So you're pro-mesh for stress urinary incontinence; correct? MR. ANDERSON: Objection.		17 18 19 20 21 22	doing a concomitant hysterectomy with sacrocolpopexy. A. Yes. Q. Do you recall, in general, that? A. Yes. Q. We were talking about the risk of
17 18 19 20 21	scale, he is pro-mesh, I am anti-mesh in the case of pelvic organ prolapse done transvaginally. Q. So you're pro-mesh for stress urinary incontinence; correct?		17 18 19 20 21	doing a concomitant hysterectomy with sacrocolpopexy. A. Yes. Q. Do you recall, in general, that? A. Yes.
17 18 19 20 21 22 23	scale, he is pro-mesh, I am anti-mesh in the case of pelvic organ prolapse done transvaginally. Q. So you're pro-mesh for stress urinary incontinence; correct? MR. ANDERSON: Objection. Go ahead.		17 18 19 20 21 22 23	doing a concomitant hysterectomy with sacrocolpopexy. A. Yes. Q. Do you recall, in general, that? A. Yes. Q. We were talking about the risk of infection. Do you recall that?

Page 334 Page 335 should not be done at the same time as a the same time as a sacrocolpopexy, the 1 2 peritoneal cavity is exposed to the same 2 sacrocolpopexy? 3 bacterial -- strike that. 3 A. I'm not aware of any. 4 4 When a hysterectomy is done at Do you know if the American Ο. 5 5 College of Gynecology has come out with a the same time as a sacrocolpopexy, the peritoneal cavity is exposed to the same statement that says that hysterectomy should 6 6 7 type of vaginal flora. 7 not be done at the same time as a 8 8 A. Flora, yes. sacrocolpopexy? 9 And you're aware that clinical 9 A. Again, I'm not aware of any. Q. 10 studies continue to be done in 10 We talked yesterday about some of 11 sacrocolpopexy cohorts that include patients 11 the different surgical procedures that you've performed for prolapse, such as 12 who have a hysterectomy at the same time; 12 colporrhaphy, sacrospinous ligament 13 correct? 13 14 A. I'm not aware of any ongoing 14 fixation, sacrocolpopexy, McCall's studies. That's not to say they're not culdoplasty and the Mayo culdoplasty. 15 15 ongoing, I'm just not aware of any. A. Culdoplasty, yes. 16 16 O. In the past couple years you've And colporrhaphy was the first 17 17 18 seen studies where a certain percentage of 18 surgery that you were trained on for pelvic the sacrocolpopexy patients did have a organ prolapse? 19 19 20 concomitant hysterectomy at the same time; 20 A. Yes. The anterior and posterior correct? 21 21 colporrhaphy. 22 A. Yes. 22 Q. And that was in the early 1990s Has the American Urologic 23 23 or mid-1990s? Q. Association come out with any type of 24 A. Mid-1990s. 1997, probably, to be 24 25 statement that says that a hysterectomy 25 specific. That's when I had my first female Page 336 Page 337 urology rotation. 1 treat apical prolapse. Anterior 1 2 2 O. And you know colporrhaphies had colporrhaphy is designed to treat anterior 3 been performed for decades before that by 3 prolapse. 4 surgeons in the field; correct? 4 Q. So the answer to the question is, 5 A. Yes. 5 no, there were no randomized, controlled trials in colporrhaphy when I started doing 6 Q. And when you began performing 6 7 colporrhaphies in 1997, there were no 7 them in 1997; correct? randomized, controlled trials with that type 8 8 A. Yes. 9 of procedure; correct? 9 Q. And for the sacrospinous ligament A. Well, I can't recall what -- what 10 fixation surgery that you were trained on 10 the data was for 1997, but in 1997 the were there any randomized, controlled trials 11 11 anterior colporrhaphy, there were not 12 in that procedure before 1990, that you're 12 anything to randomize it to. There were 13 13 aware of? 14 tissue repairs. 14 A. I would have to review the 15 15 literature. I am not aware. I am not aware of any meshes used at that point in time transvaginally Q. As you sit here today, you cannot 16 16 for anterior colporrhaphies. So, again, to identify any randomized, controlled trials 17 17 have a randomized, controlled study, you 18 with sacrocolpopexy before 1990; correct? 18 have to have something to randomize it to. A. I'd have to -- to answer your 19 19 20 Q. Correct. So there were no 20 question very specifically, as I sit here right now, no, I would be unable to come up 21 randomized, controlled trials for 21 22 colporrhaphy versus sacrospinous ligament 22 with any; however, give me 15 minutes on fixation; correct? PubMed, I'd come up with a large number. 23 23 Q. When we take a break, I'll give 24 A. Those were going after different 24 25 problems. Sacrocolpopexy is designed to 25 you 15 minutes to look on PubMed, and I want

Page 338 Page 339 you to identify all of the randomized, Q. The Mayo McCall culdoplasty, had 1 2 controlled trials before 1990 with 2 that been studied in any randomized, controlled trials before you began doing it? 3 sacrospinous ligament fixation that you are 3 4 4 A. What would be the random -- what able to come up with. 5 5 would be the control group in that? A. So --6 6 Q. I'm not the doctor. I'm asking MR. ANDERSON: Objection. 7 You said sacrocolpopexy before. 7 you, were there any randomized, controlled 8 8 trials with the Mayo McCall's culdoplasty? MR. SNELL: No. I --9 THE WITNESS: You said 9 A. Well, I have to know what it's 10 sacrocolpopexy and the sacrospinous. 10 randomized to. It's a very vague question Because you're going to have to be very 11 for me. Randomized to people driving a car, 11 specific what we're going to be comparing. 12 heart surgery, or what? 12 O. No. Of course, randomized to 13 And I'll need to have a computer that can 13 other prolapse surgeries, Doctor. 14 access to and print off the manuscripts. 14 A. Well, which one is the --15 MR. SNELL: Give me one second. 15 I thought my question was sacrospinous. I'm not talking about randomizing 16 16 Q. to people driving cars and things like that. 17 Okay. I see what you're 17 18 saying. 18 A. Yeah. That was an example. I BY MR. SNELL: need to know, randomized to which one? 19 19 20 20 Because, again, there's going to be multiple Q. The McCall's culdoplasty that you were performing during your training, had 21 different possible ones to be randomized to. 21 22 that been studied in a randomized, 22 Q. What are the ones that Mayo McCall's culdoplasty could be randomized to? 23 controlled trial? 23 24 A. I'm not aware of any on the top 24 A. It could be to sacrospinous 25 25 fixation, it could be to McCall's of my head, no. Page 340 Page 341 culdoplasty, it could be to sacrocolpopexy. 1 Now, did you testify yesterday 1 2 When you began performing the 2 that your instructors did not let you 3 Mayo McCall's culdoplasty, were you aware of 3 actually perform the sacrospinous ligament any randomized, controlled trials that fixation during your fellowship? 4 4 5 studied it compared to the McCall's 5 There were two instructors that I 6 6 worked with most significantly, two GYNs, culdoplasty? 7 7 the chair GYN at Baylor and then the other A. I am not -- sitting here right 8 8 now, no, I'm not aware of any. one was Dr. Cone, who was also on staff at Q. When you began performing the 9 9 Baylor. Mayo McCall's culdoplasty, were there any 10 The chair of the department at 10 randomized, controlled trials comparing it Baylor, he performed the procedure 11 11 to sacrospinous ligament fixation? 12 completely, palpation. It is his estimate 12 A. As I'm sitting here right now, that we did so few that it would be 13 13 difficult to become proficient in it. 14 no, I cannot recall that. 14 15 Q. When you began performing the 15 Dr. Cone never performed a sacrospinous Mayo McCall's culdoplasty, were there any fixation. That's who I learned 16 16 randomized, controlled trials comparing it 17 17 sacrocolpopexy from. 18 to sacrocolpopexy? 18 Q. So the chair at your fellowship A. As I'm sitting here right now, I did not allow you to perform the 19 19 20 sacrospinous ligament fixation surgery can't recall it. 20 during the fellowship; correct? 21 Q. Is it correct that during your 21 A. He didn't -- I assisted him. So 22 fellowship training, you observed the 22 sacrospinous ligament fixation being he was the one who actually put the needles 23 23 24 performed? 24 through. 25 25 A. That is correct. How did you assist him during the Q.

Page 342 Page 343 elevating the vaginal mucosa off the 1 sacrospinous ligament fixation? 1 2 A. As far as initial dissection, 2 underlying tissues, and then Dr. Law --3 actually, I believe it was Dr. Law was the retraction, holding sutures, closure. 3 4 O. And this was in 1999 to 2000? 4 chairman but that I could be wrong on --5 A. July of '99 to June of 2000. 5 Q. Okav. 6 6 -- would then take over and do Q. Are you aware that other Α. 7 fellowship programs in either the type of 7 the remainder of the dissection. 8 curriculum you were in for urologists or 8 O. And the retraction, how did you 9 9 urogynecology had fellows who actually do that? passed the suture through the sacrospinous 10 10 Α. That is just with -- I mean, I 11 ligament -- through the sacrospinous 11 can't recall the procedure exactly, but it 12 ligament during that procedure? 12 would be -- you have some form of either malleable retractor, hand-held retractor of 13 MR. ANDERSON: Objection as to 13 14 time period. 14 some sort exposing the underlying tissue as best you can, which is somewhat difficult. 15 THE WITNESS: Yeah. I cannot 15 O. So it can be somewhat difficult 16 -- I cannot, you know, comment on what 16 happened in other programs but I fully to expose the underlying tissue during the 17 17 18 suspect they did. I have no reason to doubt 18 retraction of a sacrospinous ligament 19 they wouldn't. 19 fixation? 20 BY MR. SNELL: 20 A. It can be difficult to set it up Q. During the sacrospinous ligament 21 appropriately, but with the correct 21 22 fixation, when you did the dissection, how 22 instruments it can be done. did you do that? 23 23 Q. And what type of instruments are 24 A. It is the vaginal dissection 24 these that you would use during the sacrospinous ligament fixation retraction? 25 through a midline vaginal incision, 25 Page 344 Page 345 1 A. Again, I can't recall. 1 that can be any size, though for vaginal 2 MR. ANDERSON: Objection. 2 surgeries they tend to be long, they tend to 3 Asked and answered. 3 be narrow. By narrow I mean 2 to 3 centimeters in width. And they can be 18 4 Go ahead. 4 5 THE WITNESS: I can't recall 5 inches long. And then you can bend it 6 anywhere, hence, the name malleable so, then 6 that exact surgery, what we used. Most 7 again, you can get a custom fit to your 7 likely, it would be something called a narrow Deaver -- D-E-V-O-R, I believe -- or 8 8 surgery. Unlike a Deaver or a renal, which there's a renal retractor which is a similar 9 is a set size and you cannot adjust it, 10 thing. It's long, narrow and deep. 10 malleables are sizes of all ranges. Again, there's the -- the Q. And when you did the dissection 11 11 for the sacrospinous ligament fixation, what 12 various different malleable retractors, 12 surgical tools did you use for that? 13 which are variable sizes, and you can adjust 13 them to custom fit them to your -- whatever A. Hydrodissection with a needle, a 14 14 15 you need and the patient's anatomy. 15 hypodermic needle filled with normal saline, BY MR. SNELL: a scalpel to dissect through to make your 16 16 O. So a malleable retractor is a incision to gain access, then you'd use 17 17 18 type of retractor, it's not an attribute of 18 Metzenbaum's scissors to actually do the elevation along with Allis clamps, spelled 19 the retractor. 19 20 A. No. It is -- it is a -- the 20 A-L-L-I-S. And then you'd use the various different retractors. And that's probably a 21 answer to your question is yes to both your 21 22 auestions. 22 fairly comprehensive list of tools. Q. Do all prolapse surgeries use 23 Q. Okay. 23 A. Malleable retractor is a piece of surgical tools? 24 24 metal, a flat piece of metal, that is long, 25 A. Well, I can't comment on all 25

		Page 346			Page 347
1	surgeries. They		1	trained me in fellowship. We used it in	
2	Q. All surgeries let me do all		2	fellowship. I already knew how to do it.	
3	surgeries that you have performed, such as		3	Q. When were you trained to do	
4	colporrhaphy, sacrospinous ligament		4	hydrodissection?	
5	fixation, sacrocolpopexy, do they all use		5	A. It would have been 1997 when I	
6	surgical tools?		6	did my female urology rotation.	
7	A. Yes.		7	Q. During your residency?	
8	 Q. And the laparoscopic and robotic 		8	A. Correct.	
9	sacrocolpopexies that you've performed also		9	Q. When was the Mayo McCall's	
10	use trocars?		10	culdoplasty first performed?	
11	A. Correct.		11	A. I would have to do a literature	
12	Q. And trocars are also used during		12	search on that. I believe it was Dr. Lee at	
13	stress urinary incontinence surgeries?		13	Mayo who did it. His career spanned the	
14	A. Technically speaking, yes. But		14	'60s into mid-2000-something. I don't know	
15	trocar is a generic term. It just means		15	exactly. Somewhere in there.	
				•	
16	it's a French word meaning three sides. And		16	Q. Can you give me your best	
17	so, again, the trocars are vastly different		17	approximation?	
18	in shape, function, but they are technically		18	A. If I were to guess, it would be	
19	trocars.		19	in the '60s and '70s.	
20	Q. You mentioned that you were		20	Q. Now, the McCall's culdoplasty was	
21	trained on hydrodissection during your		21	a procedure that was before the Mayo	
22	fellowship in connection with sacrospinous		22	McCall's culdoplasty; correct?	
23	ligament fixation; correct?		23	A. I don't know. I would suspect it	
24	A. Specific I was trained prior		24	was because the Mayo culdoplasty is somewhat	at l
25	to that in residency. I wouldn't say they		25	of a variation of the McCall's, and so I	
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		Page 348			Page 349
1	don't know the exact chronology of those.	Page 348	1		Page 349
1 2	don't know the exact chronology of those. O. That's what I thought your	Page 348	1 2	A. Yes.	Page 349
2	Q. That's what I thought your	Page 348	2	A. Yes.Q. Does the da Vinci robot have	Page 349
2 3	Q. That's what I thought your testimony was yesterday, that the Mayo	Page 348	2 3	A. Yes.Q. Does the da Vinci robot have tools that allow dissection?	Page 349
2 3 4	Q. That's what I thought your testimony was yesterday, that the Mayo McCall's culdoplasty is similar to the	Page 348	2 3 4	A. Yes.Q. Does the da Vinci robot have tools that allow dissection?A. Yes.	Page 349
2 3 4 5	Q. That's what I thought your testimony was yesterday, that the Mayo McCall's culdoplasty is similar to the original McCall's culdoplasty but it has	Page 348	2 3 4 5	A. Yes.Q. Does the da Vinci robot havetools that allow dissection?A. Yes.Q. Does the da Vinci robot have	Page 349
2 3 4 5 6	Q. That's what I thought your testimony was yesterday, that the Mayo McCall's culdoplasty is similar to the original McCall's culdoplasty but it has some different anchoring technique or	Page 348	2 3 4 5 6	 A. Yes. Q. Does the da Vinci robot have tools that allow dissection? A. Yes. Q. Does the da Vinci robot have tools that allow parts of the body to be 	Page 349
2 3 4 5 6 7	Q. That's what I thought your testimony was yesterday, that the Mayo McCall's culdoplasty is similar to the original McCall's culdoplasty but it has some different anchoring technique or location.	Page 348	2 3 4 5 6 7	 A. Yes. Q. Does the da Vinci robot have tools that allow dissection? A. Yes. Q. Does the da Vinci robot have tools that allow parts of the body to be grafts by the robot? 	Page 349
2 3 4 5 6 7 8	Q. That's what I thought your testimony was yesterday, that the Mayo McCall's culdoplasty is similar to the original McCall's culdoplasty but it has some different anchoring technique or location. A. Subtle, mild differences.	Page 348	2 3 4 5 6 7 8	A. Yes. Q. Does the da Vinci robot have tools that allow dissection? A. Yes. Q. Does the da Vinci robot have tools that allow parts of the body to be grafts by the robot? A. Yes.	Page 349
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Page 350 Page 351 1 note that the traditional non-mesh POP 1 But what I'm saying is, at the 2 repairs have failure rates up to 30 to 40 2 time these data were published on traditional non-mesh POP repairs, the 3 percent; correct? 3 4 failure rates were 30 to 40 percent, as A. I note that -- well, I have to 4 reported back then; correct? 5 5 see what page you're on. Q. Page 14 is one of the places A. Correct. As you've stated there, 6 6 7 where you say that. 7 yes, in the literature failure rates were 8 8 A. Okay. Yes. You have to read in reported up to 30 to 40 percent. 9 the totality of that sentence. The 9 Q. In fact, Doctor, in the 10 misconceived notion that traditional repairs 10 literature failure rates were reported at 11 have failure rates up to 30 to 40 percent. 11 over 50 percent; correct? 12 Q. The traditional non-mesh POP 12 A. I'd have to look at that. I 13 repairs had failure rates up to 30 to 40 13 don't know what reference you're talking 14 percent when they were originally published; 14 about. If you show it to me, I could review 15 correct? 15 that. 16 A. Well --16 Q. Turn to Page 23, Doctor. Okay. I'm there. 17 MR. ANDERSON: Objection. 17 Α. 18 THE WITNESS: -- I mean, I'd 18 Q. Now, Figure 2 you have the have to say that I put a lot of thought into different shapes of the Prolift® meshes; 19 19 what I said here and you're deleting "the 20 correct? 20 misconceived notion." 21 21 A. Correct. 22 MR. SNELL: No. No. I 22 Total, anterior and posterior; Q. 23 23 correct? understand what your position is, Doctor. THE WITNESS: Okay. 24 24 Α. Yes. 25 BY MR. SNELL: 25 Q. From where did you obtain this Page 352 Page 353 Figure 2? 1 mean, as far as the -- how the shapes got 1 A. As I recall -- because, again, 2 2 involved. I've gone through so many documents -- as I 3 3 Q. Okay. I'm not sure if I asked recall, I got this off the Internet. 4 you this yesterday: When was the last time 5 Now, the shapes -- let me back 5 you did a transobturator-placed sling? Q. 6 A. Last week. Yeah, it would have up. 6 7 7 been last week sometime, I believe. I do a The Prolift® meshes are 8 polypropylene meshes; correct? 8 large number and so I believe I did one last 9 A. Correct. 9 week. If not, then it was the week before Q. And the shapes of the Prolift® 10 that. 10 meshes depicted in Figure 2 of your report And when you perform a 11 11 Q. at Page 23, those shapes were assessed by 12 transobturator sling placement, is it 12 correct that you go in through the 13 surgeons; correct? 13 transobturator space? 14 A. I have no idea who assessed them. 14 15 Q. Isn't it your understanding, 15 A. I go through the obturator Doctor, that the French TVM surgeons 16 foramen. 16 assessed and determined these particular 17 17 Q. And you use trocars during that 18 shapes for the Prolift® mesh? 18 procedure? A. My understanding is the TVM 19 19 Α. 20 surgeons had a large piece of Gynemesh® and 20 Is the obturator foramen the same O. they cut them. I have seen in their 21 area where the anterior Prolift® mesh 21 22 documents -- excuse me -- their manuscripts 22 trocars pass? They both go through the 23 shapes. 23 Α. 24 I don't know who was all 24 obturator foramen. involved in the design of this product, I 25 Q. When you do your obturator 25

Page 354 Page 355 1 foramen passage during a transobturator 1 You would agree that dissections 2 sling, is that a blind passage? 2 for any pelvic organ prolapse surgery must be carefully performed; correct? 3 A. Yes. 3 4 O. At the top of Page 30 of your 4 A. Correct. 5 5 During the sacrocolpopexy report, Doctor --Q. 6 A. Okay. Page 30. 6 procedures that you perform, Doctor, do you 7 -- here you're talking about the 7 ever trim or make any alterations at all to 8 surgical technique with Prolift® and in 8 the Y-shape mesh? particular you are discussing the dissection 9 A. Yes. 10 of the vaginal tissue off of the bladder and 10 MR. ANDERSON: Objection. 11 surrounding tissues must be carefully 11 Asked and answered. performed so as to avoid injury. 12 12 Go ahead. Do you see where I'm at? 13 13 THE WITNESS: Yes. I see on 29 start talking about 14 14 BY MR. SNELL: hydrodissection, incisions made. Oh, here 15 15 Q. Under what circumstances would you go. Yes, starting on the bottom of 29. you do that? 16 16 The dissection of the -- yes, I see that. 17 17 MR. ANDERSON: Same objection. 18 Q. So we're at the same place? 18 Go ahead. THE WITNESS: The mesh as it 19 Yes. Top of Page 30. 19 Α. 20 So you're talking about the 20 comes in the box is quite large. The dissection of the vaginal tissue off of the anterior and posterior limbs are quite long 21 21 bladder and surrounding tissues must be and so is the tail, so you have to trim it 22 22 carefully performed so as to avoid injury; to customize it to the patient's size. 23 23 24 correct? 24 BY MR. SNELL: 25 A. Yes. 25 Q. Do you also at times have to trim Page 356 Page 357 the mesh you use during the sacrocolpopexy 1 polypropylene mesh to the sacrum in the same 1 2 2 because of findings you encounter once you location? enter the abdomen and see the surgical field 3 3 A. We are -- the exact same, no, but in which you're working, such as scarring or 4 we are very, very close. We're looking to 5 any other medical condition you may 5 the S-2, 3, 4 region, the promontory. We 6 encounter, Doctor? may vary half centimeter or more between 6 A. No. The only thing -- the only 7 7 patients. 8 reason we trim it is because preoperatively, 8 Q. You would agree that with any we don't know the full extent of the vaginal 9 pelvic organ prolapse surgery, even in the length and its relationship to the sacrum. 10 hands of the most highly skilled surgeon, 10 So that's why when it comes in there can be significant complications; 11 11 the box, the actual device is quite long, so 12 correct? 12 we always have to trim it to shorten the 13 13 A. Yes. limbs and the tail. But it would be no Turn, if you would, to Page 38 of 14 14 Q. 15 bearing upon what we find inside the 15 your report, Doctor. patient's body, it's just the vaginal length Okay. 16 16 Α. relative to the sacrum. And I'm on the paragraph that 17 17 18 Q. Is it correct that you perform 18 begins, "Also, very interesting data has standard mesh attachment to the -- strike emerged." 19 19 20 20 Are you with me? that. 21 Is it correct that you attach 21 Α. Yes, I see it. 22 one part of the polypropylene mesh that you 22 Tell me what studies or data you use in sacrocolpopexy to the sacrum? are referring to when you say, "Also, very 23 23 interesting data has emerged this" -- it 24 A. Correct. 24 25 25 should be "that"; right? Do you always attach that Q.

Page 358 Page 359 1 A. This shows -- yeah, that. Yeah. 1 subjective improvement compared with women 2 Grammatical error, yeah. 2 of -- with lesser degrees of support, is Q. What studies or data are you there a clinical study in humans that 3 3 4 4 demonstrates that, lower quality of life and referring to and relying upon for the 5 5 subjective improvement? statement, also, comma, very interesting data has emerged that shows that women 6 A. The one that I can think of off 6 7 following POP procedures that have perfect 7 the top of my head was Jacquetin. That's 8 8 vaginal support actually have a lower OOL the French gentleman, who, again, I believe 9 and subjective improvement compared with 9 he is in the TVM study, a lecture I read of 10 women with lesser degrees of support? 10 his in the IUGA meeting in Lake Como, Italy, 11 A. Well, if we continue down, we 11 2009, talking about the dynamic nature and 12 have that reference at the bottom which is 12 fixed and contraction results in pelvic pain where he had a 19.6, he referred to it as 13 referencing internal documentation, 13 depositions I've read, these manuscripts painful contraction or painful pelvis --14 14 that are referenced, specifically that the painful fixation. I'd have to look at the 15 15 vagina and the pelvis is dynamic, and that's exact study, how he phrased it. 16 16 what is evolving the thought process, that O. Was this based upon quality-17 17 18 fixed is not good, movement is good. 18 of-life scale scores? A vagina, the pelvic floor A. I did not see that referenced in 19 19 20 needs to be more like, for lack of a better 20 his -- in his presentation. phrase, like a trampoline as opposed to like 21 Q. Okay. Turn to Page 41. 21 plywood. There has to be give to it to 22 22 Are you critical of the use of accommodate movement. POPQ scoring in prolapse studies? 23 23 24 Q. For the statement that they 24 Α. No. 25 actually have a lower quality of life and 25 Is there any other anatomic Q. Page 360 Page 361 prolapse scoring classification system that 1 at 12 months after surgery, you are 1 2 2 you are aware of that has been endorsed and referring to the POPO scoring? 3 recognized by the International Continence 3 A. I am referring -- I'd have to look at the reference specifically, which we 4 Society? 4 5 A. Well, there's the Baden-Walker 5 have down there, the Ethicon internal 6 documents. I believe that we're referring grading system, B-A-D-E-N-Walker. 6 7 O. Was that system before or after 7 to anatomic failure, so anatomic POPQ the POPQ system was recognized by ICS in 8 8 failure. 9 1997, '98? 9 MR. ANDERSON: Next time you A. I --10 10 get to a breaking point. MR. ANDERSON: Objection. MR. SNELL: Okay. 11 11 12 12 Go ahead. BY MR. SNELL: 13 MR. SNELL: Let me clean it up, 13 Q. When you talk about the complication rates with Prolift®, you note 14 then. 14 15 BY MR. SNELL: 15 that the true incidence is not known due to Q. Was the Baden-Walker system multiple factors. 16 16 before the POPQ system? 17 17 Α. Yes. 18 A. It pre-existed it, yes. 18 Do you know if complications with Q. Page 41, a little ways down in colporrhaphies are routinely submitted to 19 19 20 that paragraph, "At this same time Ethicon the MAUDE database? 20 21 knew." 21 A. Standard non-tissue repairs would 22 Do you see me there? 22 not be because my understanding is the MAUDE Yes. database is medical device recording, and so 23 23 Α. since there's no implant or substance put 24 When you note that the French 24 results showed an 18.4 percent failure rate 25 in, it should not be reported. 25

Page 362 Page 363 1 Q. In your report you discuss 1 developed after his initial report was 2 granulation tissue; correct? 2 filed. 3 3 A. Yes. And with regard to that first 4 Not all granulations lead to mesh 4 point, I would just state that Dr. Elliott O. 5 5 is here, he's -- for two days and he is exposure; correct? 6 6 prepared to answer any questions that A. Correct. 7 MR. SNELL: We can take a 7 counsel may have with regard to his review 8 8 of the Pamela Wicker case and the Linda break. 9 9 Gross case and that it's going to be (Recess, 9:20-10:13 a.m.) 10 MR. ANDERSON: Can I make my 10 virtually impossible, given his schedule at 11 statement on the record now? 11 Mayo, to have him back for a deposition, to 12 MR. SNELL: Oh, yes. Of 12 sit for a deposition to answer questions about those two prior to the trial as it is 13 course. Of course. 13 14 MR. ANDERSON: So counsel has 14 currently scheduled. 15 referred a couple of times to the fact that 15 And so I would just ask that if Ethicon has, in fact, filed a Motion to counsel has any questions, even if later on 16 16 exclude the supplemental report of that part of his deposition is stricken and 17 17 18 Dr. Elliott, and that Motion is on file with 18 his opinions in that regard are excluded, that that would be a better time to deal 19 the Court. 19 20 20 with that rather than waiting to see how the Two points that I would like to 21 make on the record regarding that. One is 21 Court is going to rule and then being in a 22 that, as far as I understand it, part of the 22 position where they don't have an subject of that Motion would be that any opportunity to depose Dr. Elliott. 23 23 24 opinions he has with regard to the Linda 24 The second point that I would Gross case and the Pamela Wicker case were like to make with regard to the Motion is 25 25 Page 364 Page 365 that the supplemental report by Dr. Elliott 1 depositions, radiology, urologic testing or 1 2 2 is not in its entirety related to just the any case-specific materials particular to 3 Pamela Wicker case and the Linda Gross case, 3 the Gross or Wicker cases before issuing his rather, there are materials that he has general report in June 2012. I will not 4 4 reiterate all of the bases in the Motion. 5 reviewed since the time of his initial 5 6 report, like depositions of Ethicon 6 Counsel is on notice of it. 7 7 employees, documents that were produced I will say, if I do choose to 8 after we would have had an opportunity to 8 ask Dr. Elliott questions about his supplemental report from November 7, 2012, 9 have him look at them prior to his initial 9 10 report, et cetera, that are also contained 10 of which there is only a single paragraph in the list of materials reviewed and he has about Mrs. Gross and a single paragraph 11 11 stated in his report, in agreement with New 12 about Mrs. Wicker and which falls well short 12 13 Jersey law, that the additional materials 13 of the New Jersey standard of setting forth that he has reviewed support his initial opinions and bases for those opinions, I am 14 14 15 opinions as set forth in his initial expert 15 not in any way waiving our Motion and our report dated June 15, 2012. arguments. 16 16 MR. SNELL: As I've stated a 17 17 Thank you. 18 couple of times during this deposition, we 18 And for the record, the are seeking and have filed a Motion to supplemental report that plaintiff and 19 19 20 exclude Dr. Elliott's, what is termed the 20 myself are referring to has been marked to November 7th, 2012, supplemental report. 21 21 this -- in this deposition as Elliott This report is, in fact, a brand-new series 22 22 Exhibit Number 2. of case-specific reports. 23 23 MR. ANDERSON: Okay. 24 Dr. Elliott testified yesterday 24 BY MR. SNELL: 25 that he had not reviewed any records, 25 Q. Now, let's do some questioning.

All right. Doctor, can you tell me the Certificat Doctor, can you tell me the Certifications						
Doctor, can you tell me the medical areas in which you are Board- certified? A. Urology. Q. Are there any urology subspecialty Board certifications? A. Pediatrics, and then it's going to be female urology, reconstructive surgery. Q. And you're not Board-certified in female urology, reconstructive surgery? A. No one is at this point. Q. Is that a Board that's coming down the road? A. June 21st is the exam. You had to submit application and your - your clinical practice, surgical practice has to be for the exam. So June 21st I'll be sitting for the exam. So June 21st I'll be sitting for the exam. So June 21st I'll be sitting for the exam. So June 21st I'll be sitting for the exam. So June 21st I'll be sitting for the exam. So June 21st I'll be sitting for the exam. So June 21st I'll be sitting for the exam. So June 21st I'll be sitting for the exam. So June 21st I'll be sitting for the exam. C. D. I want to focus on the time period after your fellowship when you came back to the Mayo Clinic. Okay, Doctor? L. Clinic or surgery, so 50 percent of my time is in one or the other, so it varies from week to week. One week will be Monday, Wednesday and Friday in the operating room with Tuesday, Thursday being clinic, the subsequent week will be just the reverse of that, Monday, Wednesday, Friday clinic and then Tuesday, Thursday OR. Q. Do you do any teaching? A. Yes. Q. When do you do teaching? A. Yes. Q. When do you do teaching? A. Yes. Q. When do you do teaching? A. Yes. Q. What time – can you tell me – do you teach medical students, residents, fellows at the Mayo Clinic? A. Yes. Q. Can you tell me about the teaching you do at the Mayo Clinic? A. Yes. Q. Can you tell me what the risk factors are for prolapse? A. Yes. Q. Can you tell me what the risk factors are for prolapse? A. Yes. Q. Can you tell me what the risk factors are for prolapse? A. Ween what they are and, fiyou can, can you tell me hem in order of you shave them his usuch an A. Ween exam. Q. What imac them is took the death of the care. Q. What time can y		•	Page 366			Page 367
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4 exam, and I passed all three. 5 A. Urology. 6 Q. Are there any urology 7 subspecialty Board certifications? 8 A. Pediatrics, and then it's going 9 to be female urology, reconstructive 10 Q. And you're not Board-certified in 12 female urology, reconstructive surgery? 11 Q. And you're not Board-certified in 12 female urology, reconstructive surgery? 13 A. No one is at this point. 14 Q. Is that a Board that's coming 15 down the road? 16 A. June 21st is the exam. You had 16 to submit application and your your 17 dinical practice, surgical practice has to 19 be reviewed and approved to be able to sit 20 for the exam. So June 21st I'll be sitting 21 for the exam. 22 Q. Did you pass your Board 22 actification for urology on the first 23 attempt? 23 certification for urology on the first 24 attempt? 25 A. Yes. 26 Can you tell me, in general, how 24 you spendy our clinical week, work week? 25 A. It's every other day either in 2 voiding dysfunction-specific topics, which the fellows are involved with that. 27 Then a subsequent week will be just the reverse of that, Monday, Wednesday, and Friday in the operating room 5 with Tuesday, Thursday being clinic, the subsequent week will be just the reverse of 7 that, Monday, Wednesday, Friday clinic and 8 then Tuesday, Thursday OR. 29 Q. Do you do any teaching? 30 Q. Yes. 31 A. No. 41 A. Yes. 42 Q. When do you do teaching? 43 A. Yes. 44 Carrier of the day? 55 A. It's every other day either in 2 usually two to three times a year on 2 voiding dysfunction-specific topics, which 3 the fellows are involved with that. 45 Then also the fired was a manual of 2 usually two to three times a year on 2 voiding dysfunction-specific topics, which 3 the fellows are involved with that. 46 The fired was a fired by a part of the year or 4 when? 47 Q. What time can you tell me 4 to you teach medicial students, residents, 16 female under the part of the year or 4 do you teach medicial students every 2 year or every other year. That would be 4 when? 48 Ween exponential pour beach a	2			2		
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subspecially Board certifications? A Pediatrics, and then it's going to be female urology, reconstructive surgery. 10 Surgery. 11 Q. And you're not Board-certified in 12 female urology, reconstructive surgery? 12 Q. What about radiology? 13 A. No one is at this point. 14 Q. Is that a Board that's coming 15 down the road? 15 down the road? 16 A. June 21st is the exam. You had 17 to submit application and your your 18 dinical practice, surgical practice has to 19 be reviewed and approved to be able to sit 20 for the exam. So June 21st I'll be sitting 21 for the exam. 22 Q. Did you pass your Board 23 certification for urology on the first 24 attempt? 25 A. Yes. 27 A. Yes. 28 Q. Can you tell me, in general, how 29 you spend your clinical week, work week? 29 A. It's every other day either in 20 for the exam. 21 clinic or surgery, so 50 percent of my time 22 is in one or the other, so it varies from 23 week to week. One week will be Monday, 24 Wednesday and Friday in the operating room 25 with Tuesday, Thursday OR. 26 Q. Do you do any teaching? 27 A. When? 28 Q. When do you do teaching? 29 A. No. 29 Q. Do you do any teaching? 20 Q. What about radiology? 21 A. No. 20 Q. What about radiology? 22 Q. What about psychiatry? 23 Q. What about infectious disease? 24 A. No. 25 A. No. 26 Q. You're not Boarded in infectious 27 diseases; correct? 28 A. Correct. 29 Q. I want to focus on the time 20 period after your fellowship when you came 21 back to the Mayo Clinic. Okay. 21 Depoid after your fellowship when you came 22 a cartification for urology on the first 28 A. Yes. 29 Q. Can you tell me, in general, how 29 you spend your clinical week, work week? 21 A. I susually two to three times a year on 29 voiding dysfunction-specific topics, which 29 times a year a medicine resident - excuse 29 me - medicine resident - excuse 20 Q. Do you do any teaching? 21 Leach Board-certified internal medicine 21 individuals. 22 Q. Do you bace certain amounts of 23 time you set aside for administrative 24 responsibilities? 25 A. No. 26 Q. On	5	A. Urology.		5	Q. I understand you're a Medical	
8 A. Pediatrics, and then it's going 9 to be female urology, reconstructive 10 surgery. 11 Q. And you're not Board-certified in 12 female urology, reconstructive surgery? 13 A. No one is at this point. 14 Q. Is that a Board that's coming 15 dwn the road? 16 A. June 21st is the exam. You had 16 to submit application and your your 17 disease; correct? 18 clinical practice, surgical practice has to 18 be reviewed and approved to be able to sit 19 Q. I want to focus on the time 20 for the exam. So June 21st I'll be sitting 21 for the exam. 22 Q. Did you pass your Board 23 certification for urology on the first 24 attempt? 25 A. Yes. 1 clinic or surgery, so 50 percent of my time 2 is in one or the other, so it varies from 3 week to week. One week will be Monday, 4 Wednesday and Friday in the operating room 5 with Tuesday, Thursday being clinic, the 6 subsequent week will be just the reverse of 7 that, Monday, Wednesday, Friday clinic and 8 then Tuesday, Thursday OR. 9 Q. Do you do any teaching? 10 A. Yes. 11 Q. What do you mean? Time of the day? 12 A. When? 13 Q. Yes. 14 A. You mean what time of the day? 15 What do you mean? Time of the year or 16 Q. What time can you tell me 17 Q. What time can you tell me 18 deflows at the Mayo Clinic? 20 A. It sach medical students, residents, 18 fellows at the Mayo Clinic? 21 A. When? 22 A. It sach medical students, residents, 23 year or every other year. That would be 24 when I'm requested to speak about general 25 year or every other year. That would be 26 year or every other year. That would be 27 year or every other year. That would be 28 when I'm requested to speak about general 29 year or every other year. That would be 20 year or every other year. That would be 21 you can, can you tell me them in order of 22 year or every other year. That would be 23 year or every other year. That would be 24 when I'm requested to speak about general 25 year or every other year. That would be 26 year or every other year. That would be 27 year or every other year. That w	6	Q. Are there any urology		6	Doctor, but beyond your standard medical	
9 f. No. 10 surgery. 11 Q. And you're not Board-certified in 12 female urology, reconstructive surgery? 13 A. No one is at this point. 14 Q. Is that a Board that's coming 15 down the road? 16 A. June 21st is the exam. You had 17 to submit application and your your 18 clinical practice, surgical practice has to 19 be reviewed and approved to be able to sit 19 to rith exam. So June 21st I'll be sitting 21 for the exam. So June 21st I'll be sitting 22 q. Did you pass your Board 23 certification for urology on the first 24 attempt? 25 A. Yes. 10 Q. I want to focus on the time 2 is in one or the other, so it varies from 3 week to week. One week will be Monday, 4 Wednesday and Friday in the operating room 5 with Tuesday, Thursday Den 6 with Tuesday, Thursday Den 7 that, Monday, Wednesday, Friday clinic and 8 then Tuesday, Thursday OR. 9 Q. Do you do any teaching? 10 A. Yes. 11 Q. When do you do teaching? 12 A. When? 13 Q. Yes. 14 A. You mean what time of the day? 15 What do you mean? Time of the year or 16 Q. What time can you tell me 17 do you teach medical students, residents, 18 fellows at the Mayo Clinic? 19 A. Yes. 19 A. Yes. 20 Q. Day ou tell me about the 21 teaching you do at the Mayo Clinic? 22 A. I teach medical students every 23 year or every other quar. That would be 24 when I'm requested to speak about general 25 when I'm requested to speak about general 26 year or every other year. That would be 27 when I'm requested to speak about general 28 year or every other year. That would be 29 when I'm requested to speak about general 29 Q. What time can you tell me in order of importance, if you have them in such an order of importance, if you have them in such an order of importance, if you have them in order of importance, if you have them in order of importance, if you have them in such an order of importance, if you have them in such an order of importance, if you have them in such an order of importance, if you have them in such an order of importance, if you have them in such an order of im	7	subspecialty Board certifications?		7	training, do you have any advanced training	
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16 A. June 21st is the exam. You had 17 to submit application and your your 18 clinical practice, surgical practice has to 19 be reviewed and approved to be able to sit 20 for the exam. So June 21st I'll be sitting 21 for the exam. 22 Q. Did you pass your Board 23 certification for urology on the first 24 attempt? 25 A. Yes. 26 Can you tell me, in general, how 27 you spend your clinical week, work week? 28 A. It's every other day either in 29 voiding dysfunction-specific topics, which 29 the followshy when you came 20 back to the Mayo Clinic. Okay, Doctor? 20 A. Okay. 21 A. Okay. 22 A. Okay. 23 Can you tell me, in general, how 24 you spend your clinical week, work week? 25 A. It's every other day either in 29 Chan you fell me about the 20 submit application and what time of the day? 20 Lan you tell me what the risk 21 a usually two to three times a year on 21 voiding dysfunction-specific topics, which 25 the fellows are involved with that. 26 In the also teach a recertification exam where every year two 27 times a year a medicine resident excuse 28 me medicine staff from around the nation 29 Q. Do you do any teaching? 30 Yes. 31 Q. Yes. 32 The Manday, Wednesday, Friday clinic and 33 then Tuesday, Thursday DR. 34 A. Yes. 35 A. It's every other day either in 36 a usually two to three times a year on 37 voiding dysfunction-specific topics, which 38 the fellows are involved with that. 4 It he also teach a 5 recertification exam where every year two 5 times a year a medicine resident excuse 6 me medicine staff from around the nation 6 orome in and it's an update course, so I 8 teach Board-certified internal medicine 9 Q. Do you have certain amounts of 9 Q. Do you have certain amounts of 19 time you set aside for administrative 19 A. Yes. 10 Do you have certain amounts of 11 individuals. 11 clinical practice, correct? 12 A. No. My responsibilities are only 13 (Can you tell me what the risk 14 factors are for prolapse? 15 A. No. My responsibilities are only 16 clinical, so I'm 100 percent clinical. 17					<u> </u>	
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12 (Pages 366 to 369)

		Page 370			e 371
1	A. Okay. If it's relative of		1	smoking; repetitive lifting; heavy lifting,	
2	importance, it depends upon whose		2	that would be a lifestyle issue; genetic	
3	perspective, the patient's or mine, because		3	predisposition. Off the top of my head,	
4	those there have been studies showing		4	that's it. I can't say that's a	
5	that there's a difference of what a patient		5	comprehensive list.	
6	wants to gain out of surgery versus what the		6	Q. Can you tell me the number of	
7	doctor expects to gain, those things.		7	sacrospinous ligament fixation surgeries you	
8	So that's not to be difficult,		8	have performed at Mayo Clinic?	
9	I just kind of need to know if I'm talking		9	A. Zero.	
10	to a patient in what they want to know		10	Q. The use of mesh in abdominal	
11	versus giving a lecture to other surgeons		11	sacrocolpopexy was a use that was developed	
12	and what to expect.		12	by physicians; correct?	
13	Q. Okay. I think we strayed off and		13	A. I don't know who developed it. I	
14	lost communication. I was looking for the		14	would I would assume it was developed by	
15	risk factors for prolapse, not		15	surgeons doing the procedure themselves.	
16	A. Okay.		16	Q. I think we discussed this	
17	Q the surgery itself. So can		17	yesterday, but surgeons were using materials	
18	you tell me the risk factors?		18	like autologous materials for sacrocolpopexy	
19	A. Oh, risk factors for prolapse.		19	and they found less than satisfactory rates	
20	I'm sorry. I misunderstood your question.		20	of recurrence, according to the medical	
21	Q. It's okay, Doctor.		21	literature; correct?	
22	A. Risk factors for prolapse:		22	A. Correct.	
23	previous surgery for prolapse; previous		23	Q. And then surgeons began looking	
24	hysterectomy; obesity; questionably,		24	towards synthetic meshes as an option to,	
25	menopause; questionably, age; indirectly,		25	hopefully, reduce that incidence of	
		Page 372		Page	e 373
1	increased recurrence; correct?		1	Q. If you were going to counsel one	
2	A. Correct.		2	of your patients on the potential risks of	
3	Q. What other procedures do you		3	an abdominal sacrocolpopexy, what risk would	
4	ordinarily do at the time of an abdominal		4	you identify to your patient?	
5	sacrocolpopexy?		5	A Diels of blooding riels of wound	
6	MR. ANDERSON: Objection.			 A. Risk of bleeding, risk of wound 	
_	111171111111111111111111111111111111111		6	infection, risk of bowel abnormalities,	
7	Go ahead.			5,	
8	-		6	infection, risk of bowel abnormalities,	
	Go ahead.		6 7	infection, risk of bowel abnormalities, specifically bowel obstruction from the	
8	Go ahead. THE WITNESS: Usually we'll be		6 7 8	infection, risk of bowel abnormalities, specifically bowel obstruction from the surgery itself.	
8 9	Go ahead. THE WITNESS: Usually we'll be putting in an doing an anti-incontinence		6 7 8 9	infection, risk of bowel abnormalities, specifically bowel obstruction from the surgery itself. Again, as long as we're being	
8 9 10	Go ahead. THE WITNESS: Usually we'll be putting in an doing an anti-incontinence procedure at the same time.		6 7 8 9 10	infection, risk of bowel abnormalities, specifically bowel obstruction from the surgery itself. Again, as long as we're being very clear we're talking about abdominal	
8 9 10 11	Go ahead. THE WITNESS: Usually we'll be putting in an doing an anti-incontinence procedure at the same time. BY MR. SNELL:		6 7 8 9 10 11	infection, risk of bowel abnormalities, specifically bowel obstruction from the surgery itself. Again, as long as we're being very clear we're talking about abdominal sacrocolpopexy because the discussion is	
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Page 374 Page 375 have not seen. It is highly unlikely and so an individual may not have 1 2 incontinence at the time of preoperatively, 2 because of the minimal manipulation of the 3 bowel at the time of the procedure. 3 it's due to -- it's occult, and when you 4 reduce the prolapse, you can uncover the 4 And then also then mesh 5 extrusion again. That would be the same 5 incontinence. So that's why I'll do a prophylactic sling now in my practice. That 6 discussion as with the abdominal 6 7 has evolved. So I warn them very clearly 7 sacrocolpopexy. 8 about the possibility of developing stress 8 And then the same as far as 9 urinary incontinence following surgery. 9 with the urinary incontinence. There's no difference there. 10 O. For the robotic laparoscopic 10 11 sacrocolpopexy what risks would you inform 11 Q. Would you also have the same discussion with regard to the risk with the 12 your patient of? 12 A. Most importantly, the 5 percent 13 13 anesthesia? risk of converting to open, meaning we would 14 14 A. Yes. Yes. not be able to accomplish the procedure 15 15 Q. Now, for the abdominal using the robot. So they have to understand 16 16 sacrocolpopexy you used the term "mesh that there's a chance they could end up with erosion" and in the robotic you said "mesh 17 17 18 an incision. 18 extrusion," and I just want to understand, is there some difference in the discussion 19 The risk of bladder injury at 19 20 the time of the procedure would be slightly 20 or was that just a difference of terms you higher than doing it open so we focus more 21 happened to use in the last minute or two? 21 A. Yeah. That -- I misspoke. It's 22 time on that. 22 23 The risk of bleeding is less in 23 extrusion. And that is a problem with our 24 our series so I don't spend too much time on 24 nomenclature at this point in time. There's that. Risk of small bowel obstruction we -- the words are too similar. It's very 25 25 Page 376 Page 377 confusing. 1 as the -- just the anesthesia itself. 1 2 2 O. If you were doing a colporrhaphy, O. Are you familiar with the CARE 3 what are the risks you would identify to 3 study that looked at abdominal 4 your patient? 4 sacrocolpopexy? 5 A. Okay. We'd have to break it up 5 A. I vaguely remember -- I -- we 6 to either anterior or posterior because I 6 don't walk around talking about the CARE 7 7 study but I remember reading it or would say the risks are going to be different between the two. 8 something. I know the authors involved with 8 9 So if you want to start with 9 it. 10 anterior colporrhaphy, same risk as far as 10 Q. For colporrhaphy do you also tell bleeding. I do -- we do not -- then your patients that they may develop de novo 11 11 12 incontinence following the procedure. 12 dvspareunia? A. We discuss it. In my practice 13 Almost always at the time of 13 anterior colporrhaphy I am putting in a and in my experience, it's been exceedingly 14 14 15 concurrent sling is my practice, again, 15 rare. because of the occult incontinence. Q. You're aware in the literature 16 16 I briefly discuss wound that it's been, de novo dyspareunia has been 17 17 18 infection; however, I just don't see that in 18 reported in over 15 percent of patients in my practice. Let's see. What else? different studies for colporrhaphy? 19 19 Inadvertent bladder injury. 20 A. Well, according to what I've read 20 And then lastly, I inform them in the depositions, according to Ethicon, 21 21 that's rare. Because they talk about 22 that I always do a cystoscopy because 22 there's the possibility of inadvertently extrusions being that rate and they called 23 23 24 obstructing a ureter. 24 it rare. 25 And then the other risks as far 25 MR. SNELL: Move to strike.

Page 378 Page 379 BY MR. SNELL: the potential risk of dyspareunia? 1 1 2 Q. I'm not asking you to 2 A. We spend some time on it. 3 However, we also talk a lot with the sexual 3 characterize one thing versus another one as 4 a concept. I'm just asking you, you're 4 history preoperatively to know if there's --5 5 aware in the medical literature that there if, number one, if they're sexually active. has been de novo dyspareunia seen in over 15 6 If they're not sexually active 6 7 percent of patients in different studies 7 and there's no anticipated future sexual 8 involving colporrhaphy? 8 activity, I do not spend much time with it. If they are sexually active, 9 MR. ANDERSON: Objection. 9 10 Go ahead. 10 then we usually state that it is -- tends to 11 THE WITNESS: You'd have to 11 be improved following it because we restore break it down to anterior versus posterior. 12 more normal anatomy. I don't guarantee that 12 but we -- we do it very -- each patient is 13 Posterior does have a higher incidence of 13 dyspareunia, anterior has less. going to be managed differently depending 14 14 So the 15 percent number, I upon where they're coming in with their 15 15 just want to make sure what study, if, sexual history at that point in time. 16 16 again, it's anterior versus posterior. O. And you're aware that the medical 17 17 18 Because, no question -- see, we haven't 18 literature reports rates of de novo 19 gotten to posterior yet. dyspareunia in patients who have undergone 19 20 When I talk about posterior 20 sacrocolpopexy -- strike that. 21 colporrhaphies, I do discuss dyspareunia in 21 You're aware that the medical a lot more detail because it is definitely a 22 22 literature reports rates of de novo larger risk with that procedure. 23 23 dyspareunia exceeding 10 percent in patients 24 BY MR. SNELL: 24 who underwent sacrocolpopexy; correct? MR. ANDERSON: Objection. 25 Q. Sacrocolpopexy, do you discuss 25 Page 380 Page 381 Go ahead. 1 Do you know, how many urology 1 2 fellowships were there in the United States THE WITNESS: Well, number one, 2 I'd like to actually see that study; 3 like the one that you attended where you 3 focused on female reconstructive prolapse 4 however, that does sound appropriate. 4 5 BY MR. SNELL: 5 surgeries, urinary incontinence surgeries, 6 Q. Pelvic organ prolapse surgery is 6 in 2005? 7 7 a fairly complex surgery; correct? A. 2005. I won't be able to give A. I would agree with that, that it 8 you a number in 2005 because it is evolving 8 9 takes learning to know how to do it. The 9 because starting in 2008 or 2009 is when the surgical dissection, the knowledge of the 10 GYN Board and the American Urologic 10 anatomy, the consequences of surgery, I Association -- or no, that's wrong. The 11 11 would agree with your statement. Board of American Urology, ABU, American 12 12 Board of Urology, when they combined to set O. It's the type of surgery that's 13 13 best performed in the hands of a specialist; up criteria for a female 14 14 15 correct? 15 urology/urogynecology fellowship. A. Well, it depends what you're So in 2005 I don't know the 16 16 defining as specialist. It needs to be done number. Currently, there are I believe like 17 17 15, 16, my last check. 18 by a urologist who's familiar with the 18 Q. Is that urology only or -pelvic anatomy and pelvic organ prolapse or 19 19 a gynecologist or a urogynecologist who's 20 It's both. 20 A. 21 familiar with it. 21 -- is that a combination of 22 A specialist, I would not say a 22 urology and urogynecology fellowships? general surgeon should do it, but it is not There is now no such thing as 23 23 urology or gynecology. All fellowships that 24 somebody who necessarily needs to have a 24 25 fellowship. 25 have been approved are combined.

		Page 382	_		Page 383
1	Q. In 1999 and 2000, when you did		1	Q. When a patient comes to you for	
2	your fellowship, how many other similar		2	prolapse, your consultation and treatment	
3	fellowships were there for urologists, such		3	are geared towards that specific patient;	
4	as yourself?		4	correct?	
5	A. Yeah. I don't know because it		5	A. Correct.	
6	was in the stages where things were coming		6	Q. And that takes into account that	
7	about so it was not an issue that it was		7	•	
			_	specific patient's symptoms; correct?	
8	discussed. I don't know. I would think,		8	A. Correct.	
9	actually, there would be fewer back then.		9	Q. And you would agree it's	
10	Q. So you would agree it's a fairly		10	important to discuss the different possible	
11	small group of surgeons who are being		11	alternative treatments with patients?	
12	trained in these fellowships currently;		12	A. Absolutely.	
13	correct?		13	Q. And you, obviously, counsel	
14	MR. ANDERSON: Objection.		14	patients on different surgical options which	
15	Go ahead.		15	you believe may be appropriate for a given	
16	THE WITNESS: Relative to the		16	case; correct?	
17	number of urologists and gynecologists being		17	A. Correct.	
18	trained every year, it is correct to say		18	Q. Let me say that again.	
19			19	, ,	
	that those going through fellowships either			As a surgeon, you, obviously,	
20	in, again, this combined fellowship, I tend		20	counsel patients on different surgical	
21	to call it female urologists because I'm a		21	options which you believe may be appropriate	
22	urologist, but the combined fellowship		22	for that particular patient; correct?	
23	percentage-wise, that would be a select		23	A. Correct.	
24	group.		24	Q. And as a surgeon, one of the	
25	BY MR. SNELL:		25	issues that would be important for a surgeon	
,	to consider with respect to the precedures	Page 384	1		Page 385
1	to consider with respect to the procedures	Page 384	1	surgeon should be competent in those	Page 385
2	is those procedures with which he or she	Page 384	2	surgeon should be competent in those particular surgical options he or she	Page 385
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	Page 386			Page 387
1	and beyond competence. Competence is the	1	I believe you testified	
2	entry level. Okay?	2	yesterday that you've never used or	
3	And so then I go for the	3	implanted Prolift®; correct?	
4	credentialling committee and I have to say,	4	A. Correct.	
5	here's what I feel comfortable doing, the	5	Q. Have you ever used or implanted	
6	procedures, and then they credential it.	6	Apogee®?	
7	You have then, I can't recall	7	A. No.	
8	exactly now, it's a one- or two-year time	8	Q. Have you ever used or implanted	
9	period that you are then observed by a	9	Perigee®?	
10	colleague competent in those procedures to	10	A. No.	
11	make sure you are performing those	11	Q. You never underwent or	
12	procedures to the highest level possible.	12	participated in any of the professional	
13	Q. So you only sought credentialling	13	education programs for Prolift®; correct?	
14	on those procedures in which you had been	14	A. Correct. I did not.	
15	trained; correct?	15	Q. You never did any cadaver	
16	A. No, not necessarily. It was yes,	16	training with respect to Prolift®; correct?	
17	but it was also in management and treatment	17	A. I did not.	
18	of pelvic organ prolapse. So it was not	18	Q. And you never underwent cadaver	
19	limiting me to the development of future	19	training with respect to the use of any mesh	
20	techniques.	20	products for prolapse repair; correct?	
21	Q. You sought credentialling with	21	A. No. I'm just trying to remember.	
22	respect to the procedures that you felt	22	In fellowship we may have had cadaver labs	
23	comfortable with? Is that a fair statement?	23	on the sacrocolpopexy because our staff was	
24	A. Yes, that is.	24	involved in AUA as far as the individual to	
25	Q. Switch to a different topic.	25	come in for learning and I may have been	
	Qi owitch to a affective topici		come in for learning and I may have been	
	Page 388			Page 389
1	involved in cadaver labs with the	1	litigation, you had never observed a surgery	_
2	sacrocolpopexy, but not transvaginal.	2	involving Prolift®; correct?	
3	Q. It's correct you never underwent	3	A. Not to my recollection, no.	
4	any cadaver lab training with respect to	4	Q. Now, have you seen surgical	
5	transvaginal placement of mesh.	5	videos of the Prolift® surgery?	
6	A. Correct.	6	A. Yes.	
7	Q. I take it you never talked with	7	Q. The surgical videos that you saw	
8	any of Ethicon's sales representatives about	8	on the Prolift® surgery were within the	
9	Prolift®?	9	context of this litigation; correct?	
10	A. I don't recall ever meeting with	10	A. Correct.	
11	one. I run it so that I very rarely have	11	Q. They were surgical videos	
12	any interaction with the industry. But when	12	provided to you by the plaintiffs' lawyers;	
13	we go to meetings, they swarm around you.	13	correct?	
14	So I could have encountered one.	14	MR. ANDERSON: Me.	
15	Q. As you sit here today, do you	15	BY MR. SNELL:	
16	have any specific recollection of having	16	Q. Mr. Anderson; correct?	
		17	A. Correct. Yes.	
17	conversations with an Ethicon sales rep	17 18		
17 18	conversations with an Ethicon sales repregarding Prolift®?	18	Q. Have you participated in any	
17 18 19	conversations with an Ethicon sales repregarding Prolift®? A. None, no.	18 19	Q. Have you participated in any professional education programs for any	
17 18 19 20	conversations with an Ethicon sales rep regarding Prolift®? A. None, no. Q. Before being engaged in this	18 19 20	Q. Have you participated in any professional education programs for any manufacturer of pelvic mesh?	
17 18 19 20 21	conversations with an Ethicon sales rep regarding Prolift®? A. None, no. Q. Before being engaged in this litigation, you had never reviewed any of	18 19 20 21	Q. Have you participated in any professional education programs for any manufacturer of pelvic mesh? A. For pelvic mesh? So participated	
17 18 19 20 21 22	conversations with an Ethicon sales rep regarding Prolift®? A. None, no. Q. Before being engaged in this litigation, you had never reviewed any of the marketing materials for Prolift®;	18 19 20 21 22	Q. Have you participated in any professional education programs for any manufacturer of pelvic mesh? A. For pelvic mesh? So participated with pelvic mesh?	
17 18 19 20 21 22 23	conversations with an Ethicon sales rep regarding Prolift®? A. None, no. Q. Before being engaged in this litigation, you had never reviewed any of the marketing materials for Prolift®; correct?	18 19 20 21 22 23	Q. Have you participated in any professional education programs for any manufacturer of pelvic mesh? A. For pelvic mesh? So participated with pelvic mesh? Q. Yeah.	
17 18 19 20 21 22	conversations with an Ethicon sales rep regarding Prolift®? A. None, no. Q. Before being engaged in this litigation, you had never reviewed any of the marketing materials for Prolift®;	18 19 20 21 22	Q. Have you participated in any professional education programs for any manufacturer of pelvic mesh? A. For pelvic mesh? So participated with pelvic mesh?	

	Connacticul Acc			
	Page 390		1	Page 391
1	A. For prolapse, no.	1	Q. Before becoming engaged in this	
2	Q. Have you ever participated in any	2	litigation, had you ever reviewed the	
3	professional education programs for a	3	Prolift® instructions for use?	
4	manufacturer of mesh used to treat stress	4	A. No, I had not.	
5	urinary incontinence?	5	Q. Before becoming involved in this	
6	A. Yes.	6	litigation, had you ever read the	
7		7		
	•	8	instructions for use for Gynemesh® PS? A. No.	
8	those?			
9	A. AMS and Coloplast.	9	Q. Before becoming involved in this	
10	Q. Now, obviously, you were never a	10	litigation, had you ever reviewed the IFU	
11	Prolift® preceptor; correct?	11	for any other mesh used in pelvic floor	
12	A. Correct. I was not.	12	reconstruction?	
13	Q. And you were never a Prolift®	13	A. Yes. The Coloplast product. And	
14	proctor; correct?	14	then I believe I was also provided one for	
15	A. No, I was not.	15	the AMS product. That was quite a long time	
16	Q. Have you ever called and spoken	16	ago but, yes, they had provided that for me.	
17	to a Prolift® preceptor?	17	Q. And the Coloplast product was a	
18	A. No.	18	sling product?	
19	Q. Have you ever called and spoken	19	A. No. They're mesh.	
20	to a Prolift® proctor?	20	Q. The AMS product was also a mesh?	
21	A. No. But I've had conversation	21	A. A mesh, correct.	
22	when I have patients referred to me with	22	Q. Is that the IntePro that you	
23	complications, I have spoken to the outside	23	referenced yesterday	
24	physician who put the device in. I don't	24	A. No. No.	
25	know if what their status was.	25	Q or something else?	
		_	5	
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	Page 392			Page 393
1		1	A. Yes.	Page 393
	A. This was something else. It was	1 2	A. Yes.	Page 393
2	A. This was something else. It was the Apogee®, Perigee®, one of those two, or	2	A. Yes. Q. Which one?	Page 393
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	A. This was something else. It was the Apogee®, Perigee®, one of those two, or Elevate®. And then the Coloplast product, I don't even recall what their name was, but the reps were pushing it. Q. Have you ever been requested by a manufacturer or a regulatory agency to consult on the contents of an instructions for use? A. No. Q. Have you ever been requested to advise on the content of a surgical technique manual? A. For a manufacturer? Q. By a manufacturer or some governmental agency. A. No. No. I mean, I've given opinions for journals in their surgical descriptions section for various different surgeries I perform but not for an industry	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	 A. Yes. Q. Which one? A. Well, that would be AMS and Coloplast also. Q. The same ones you earlier referred to. A. Yes. And then also for their suprapubic sling and transobturator sling and their male incontinence procedure for Coloplast. Q. Did you have any criticism of those surgical technique manuals? A. What I'm looking at well, it depends on what procedure, if I'm coming in with little knowledge or a lot of knowledge. If I have a lot of knowledge, I'm usually going to be quite critical because I'm going to see where I feel there are deficiencies or warnings. If I am a novice to it, like 	Page 393
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Page 394 Page 395 And you still consider it an know enough to know what the pros and cons 1 2 were of that procedure? Is that what you're 2 important option in your armamentarium today 3 saying? 3 to treat women with stress urinary 4 4 A. What I'm saying is, when I incontinence; correct? 5 5 started doing transobturator in, whenever A. For a select group of that was, 2002 to 2004 -- and, again, I 6 individuals, yes, it's a very important part 6 7 stated that I believe I was the first one to 7 of my practice. 8 8 do it in the State of Minnesota -- no one O. Prior to becoming involved in 9 9 this litigation, you had never seen a had experience in it. 10 It was designed, invented and 10 patient brochure for Prolift®; correct? 11 patented in France and so the U.S. 11 A. Correct. introduction was, as I recall, through 12 Prior to becoming involved in 12 Q. Mentor, because they had the patent on it. 13 13 this litigation, had you seen the patient So no one had knowledge of it. brochure for any prolapse mesh product? 14 14 I understood vaginal A. Yes. The Coloplast and the AMS 15 15 dissections, I did not understand the 16 16 product. transobturator route because no one had ever 17 17 O. Did you ever use those patient 18 heard of it before. So that's why I say as 18 brochures? far as novice. I had knowledge of A. No. No. It was the 19 19 20 anti-incontinence procedures but not the 20 representative, it was the reps for transobturator route. Coloplast, it was the vice-president of AMS 21 21 22 Q. And as you gained experience with 22 who gave me the brochures, and I never did using the transobturator route, you became do the procedure nor hand them out to any 23 23 24 more and more comfortable with it? 24 patients. 25 A. Yes. 25 Q. Do you know if other surgeons at Page 396 Page 397 Mayo Clinic were doing those procedures? 1 surgeon, like yourself; correct? 1 2 2 MR. ANDERSON: Those Correct. 3 3 Would you ever perform a surgery procedures? 4 MR. SNELL: The ones that you on a patient who came to you who said, 5 identified, the Coloplast and the AMS mesh 5 Doctor, I've looked at a patient brochure 6 6 and I want to have this particular type of procedures. 7 7 surgery without actually counseling and THE WITNESS: Well, no, those 8 8 -- to the best of my knowledge, nobody at examining the patient? Mayo does any mesh for pelvic organ 9 Α. No. prolapse, for transvaginal route. 10 Do you know what patient 10 BY MR. SNELL: brochures were available to patients in your 11 11 O. Do you ever use patient brochures 12 clinic at Mayo -- strike that. Let me back 12 13 -- strike that. 13 14 Before this, becoming involved 14 Would you actually give these 15 in this litigation, did you ever use patient 15 patients the brochures for the urinary brochures for sling products? incontinence products? 16 16 A. I -- yes, I give the patient A. Yeah. Either myself or my 17 17 18 brochures for the transobturator sling by 18 physician assistant would. Coloplast, the suprapubic sling -- well, Q. Did you keep them in your office 19 19 actually, they're both, they're encompassing 20 or were they out in the waiting area or some 20 both, suprapubic and transobturator, and 21 other place? 21 22 they also give the brochures for the 22 A. In my office. We are not allowed artificial urinary sphincter. at Mayo to have any industry products out. 23 23 Q. And the patient brochures are 24 24 Q. Did you prepare any materials 25 designed to be used in consultation with the 25 yourself for your patients for whom you

Page 398 Page 399 1 1 would use mesh in to treat their prolapse? Go ahead. 2 2 THE WITNESS: I would first A. No. 3 3 Q. In the course of your teaching, counsel them that any patient that calls up 4 did you train any residents or fellows on 4 who has had a mesh, whether it be sling or 5 5 how to treat mesh erosions or exposure that prolapse, to have a high index of suspicion 6 if a patient calls up with a discharge. 6 occur following a sacrocolpopexy? 7 A. In the past. But we haven't had 7 Okay. So, first of all, it's a warning. 8 8 one in six or seven years. So the current Always be thinking about that. 9 group of fellows have not -- residents have 9 Then I would have them say that 10 not seen it. 10 we cannot treat this over the telephone, 11 Q. Have you trained them on -- let 11 meaning I can't just call in something. You 12 me re-ask it. 12 always have to see the patient, talk to them, get a good history, get a kind of feel 13 Have you trained residents or 13 for what's going on and the severity of it, 14 fellows on how to treat mesh erosion or 14 then do a very thorough pelvic exam. 15 exposure should it occur following a 15 Possibly, if there's any urinary complaints, 16 sacrocolpopexy? 16 A. Yeah. I say if trained as in then do a cystoscopy, make sure there's no 17 17 18 past tense, yes, I have. 18 bladder perforation or erosion specifically. Q. And if you had a mesh erosion or Then on the pelvic exam 19 19 20 exposure with a sacrocolpopexy, how would 20 specifically with a speculum and also just a you go about telling residents or fellows bimanual because sometimes you can't see it 21 21 the step-wise progression of treating that 22 22 but you can feel it so you have to do both, complication following the sacrocolpopexy 23 23 and you have to take your time because the 24 procedure? 24 small ones are easier to miss, the large 25 MR. ANDERSON: Objection. 25 ones are not. Page 400 Page 401 You also have to, when you do 1 Α. Correct. 1 2 your exam be looking, is there a discharge, 2 And if you believe that you need 3 does it look erythema, erythematous, is 3 to do a mesh excision of the mesh exposure following a sacrocolpopexy, what route would there a specific amount of granulation 4 5 tissue? Then once all those things are 5 you go in to -- first to do that mesh 6 done, then you have to evaluate, again, like 6 rescission? 7 7 we talked about vesterday, the size of the Again, that depends upon all the 8 different factors and things. But I have to 8 infection, all those things. 9 BY MR. SNELL: 9 think back to, again, the last time we had 10 Q. And then the same would hold true 10 one, which was roughly seven years ago, when then in the case of a sacrocolpopexy, as our we swapped over to IntePro. 11 11 12 discussion yesterday, you would attempt to 12 Sacrocolpopexy meshes, you have treat it most conservatively first. to be careful what you're going after 13 13 A. Dependent upon, yeah, the because that's a lot -- there's mesh that 14 14 15 severity of the problem. But yes, you --15 extends all the way up to the sacrum. So you start as conservative as possible for you're going to be then counseling the 16 16 patient on as far as the dissection, if it's 17 that given patient. 17 18 Q. So for a mesh exposure or erosion 18 just limited, just cutting it out. with sacrocolpopexy, you would still try to If -- now, I have not seen this 19 19 treat it as conservative as possible for a 20 in my practice, however, I've talked to my 20 21 given patient. 21 urogynecology colleagues about this. If you 22 A. Correct. 22 have a patient who comes in with, obviously, Q. And based upon the patient's a purulent discharge, a large, gaping hole 23 23 and a large amount of mesh coming back and 24 unique presentation and your findings on 24 25 the patient has systemic symptoms of 25 exam.

Page 402 Page 403 1 infection, now you're probably going to be 1 about, the patient-specific issues. 2 approaching that transabdominally. 2 Q. So it's correct, then, that if Q. Is it correct that you would try 3 you can do a transvaginal mesh rescission, 3 4 to do a transvaginal mesh excision following you prefer to do so over the transabdominal 4 5 5 a sacrocolpopexy if -- strike that. mesh excision; correct? Is it correct that you would 6 A. If it can be safely and 6 7 first attempt -- let me see how I can say 7 successfully accomplished transvaginally, 8 8 that is, no question, my preferred route. this. Q. And that's because transabdominal 9 9 If you have a patient who has a surgery is a major and morbid surgery; 10 mesh excision following a sacrocolpopexy and 10 11 it is a --11 correct? 12 It's mesh exposure. 12 A. That is fair to say, yes. Α. 13 Yeah. I'll just call it that. 13 O. Before becoming involved in this Q. 14 Yeah. 14 litigation, had you ever looked at mesh that had been removed from a patient under a 15 If you have a patient, Doctor, 15 who has a mesh exposure following microscope? 16 16 sacrocolpopexy and you believe that you can 17 17 A. No. 18 do the mesh excision transvaginally or 18 Q. Have you done that since becoming 19 transabdominally, which option do you involved in this litigation? 19 20 choose? 20 A. Not of my own patients. I've seen photographs and microscopies and A. Well, I can always do it 21 21 transabdominally. That's a major and morbid 22 22 papers. procedure. So the question is, can I 23 23 Q. Prior to being engaged as an accomplish it transvaginally? And that's 24 expert witness in this matter, had you ever 24 when all those other criteria I talked 25 25 performed any examination of the porosity of Page 404 Page 405 meshes? 1 litigation. 1 2 2 The internal documents were A. No. documents that Mr. Anderson or the other 3 Q. You don't hold yourself out to be 3 4 a polymer chemist; correct? 4 plaintiffs' lawyers gave you; correct? 5 Α. That is correct. 5 Correct. 6 If you were counseling a patient 6 0. Before becoming involved in this 7 7 on the sacrospinous ligament fixation litigation, had you ever reviewed any other surgery, what risk would you identify to her 8 company's internal documents? 8 9 with that procedure? 9 A. Only pertaining to that patent A. Well, I wouldn't have that 10 infringement case. 10 counsel, consultation because I would send The deposition transcripts, those 11 11 were given to you by Mr. Anderson or 12 them to my urogynecology colleagues. 12 Q. Because you don't do sacrospinous plaintiffs' counsel; correct? 13 13 ligament fixation procedures; correct? A. Correct. Yes. 14 14 15 A. That is correct. 15 The medical literature, the Can you tell me what independent manuscripts that you reviewed, were those 16 Q. 16 given to you by plaintiffs' counsel as well? research you did in connection with your 17 17 18 role as an expert in this litigation, other 18 They gave me a few. So roughly than reviewing the materials that we're looking at 200 or so manuscripts in my 19 19 plaintiffs' counsel provided to you? report and supplemental report. When this 20 20 all started, I believe Mr. Anderson gave me 21 A. Well, I reviewed, as you 21 20, maybe 30. So everything else is from 22 mentioned, the internal documents, I 22 reviewed roughly, what, 200 manuscripts, 23 23 me. scientific journal manuscripts, and then the 24 24 Q. So the independent research you 25 depositions, which would be the -- from the 25 did besides reviewing the materials that

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Ì	Pag	e 406		Page 4	107
1	plaintiffs' counsel sent to you was you		1	THE WITNESS: or never	
2	reviewed some of the medical literature and		2	anticipate being employed by the FDA.	- 1
3	manuscripts.		3	BY MR. SNELL:	- 1
4	A. Yeah. It's fair to say that		4	Q. Have you ever been a consultant	- 1
5	except for what I received from Mr. Anderson		5	to the FDA?	- 1
6	and colleagues, everything would be journal		6	A. No. The closest would be through	- 1
7	reviews.		7	that Public Citizen, Ralph Nader's group,	- 1
8	Q. Do you know any of the study		8	where I had comments read at the FDA. But I	- 1
9	investigators involved in clinical studies		9	wouldn't think I would be a consultant for.	- 1
10	concerning Gynemesh® PS?		10	Q. Has the FDA ever paid you to be a	- 1
11 12	A. No, I I don't know any of those.		11 12	consultant to provide information to them? A. No.	- 1
13	Q. Do you know Doug Hale?		13	Q. Have you ever served on an FDA	- 1
14	A. I don't recognize the name.		14	advisory committee board?	- 1
15	Q. Do you know anyone involved in		15	A. No.	- 1
16	the Prolift® clinical studies?		16	Q. Have you ever testified at any	- 1
17	A. Not that I know of, no.		17	government institution, setting aside, you	- 1
18	Q. Now, you've never been employed		18	know, the patent case and any other	- 1
19	by the FDA; correct?		19	depositions or trial testimony you've given?	- 1
20	A. No.		20	A. No.	- 1
21	Q. I'm not correct?		21	Q. Have you ever testified at an FDA	- 1
22	A. No. You are correct. I have		22	advisory committee?	- 1
23	never been employed		23	A. No. Again, other than that	- 1
24	MR. ANDERSON: Your bad		24	Public Citizen comments. But I was not	- 1
25	question.		25	personally there.	-1
	_				
4		e 408	1	Page 4	109
1 2	Q. Have you reviewed the federal regulations that pertain to medical devices?		1 2	Q. So it's correct that you were not involved in the human clinical trials with	- 1
3	A. No.		3	regard to this artificial urinary sphincter;	- 1
4	Q. Have you ever reviewed any FDA		4	correct?	- 1
5	regulations pertaining to devices before		5	A. I was not involved in the	- 1
6	becoming engaged as an expert witness in		6	implantation. I was involved heavily as far	- 1
7	this case?		7	as the write-up, the documentation. And	- 1
8	A. No.		8	then timing, I was sent down to my	- 1
9	MR. ANDERSON: Off the record.		9	fellowship so I left. I did the work but	- 1
	(Discussion off the record.)		10	didn't get to do the surgery.	
10			11		
10 11	BY MR. SNELL:		11	Q. You've never been involved in a	-
11 12	Q. Have you ever been involved in		12	clinical trial designed to evaluate the	
11 12 13	Q. Have you ever been involved in the clinical trial designed to evaluate the		12 13	clinical trial designed to evaluate the safety and efficacy of a prolapse device;	
11 12 13 14	Q. Have you ever been involved in the clinical trial designed to evaluate the safety and efficacy of a medical device?		12 13 14	clinical trial designed to evaluate the safety and efficacy of a prolapse device; correct?	
11 12 13 14 15	Q. Have you ever been involved in the clinical trial designed to evaluate the safety and efficacy of a medical device? When I say clinical trial, I mean in humans.		12 13 14 15	clinical trial designed to evaluate the safety and efficacy of a prolapse device; correct? A. Correct.	
11 12 13 14 15 16	Q. Have you ever been involved in the clinical trial designed to evaluate the safety and efficacy of a medical device? When I say clinical trial, I mean in humans. A. Yes.		12 13 14 15 16	clinical trial designed to evaluate the safety and efficacy of a prolapse device; correct? A. Correct. Q. You've never been involved in a	
11 12 13 14 15 16 17	Q. Have you ever been involved in the clinical trial designed to evaluate the safety and efficacy of a medical device? When I say clinical trial, I mean in humans. A. Yes. Q. What was that?		12 13 14 15 16 17	clinical trial designed to evaluate the safety and efficacy of a prolapse device; correct? A. Correct. Q. You've never been involved in a clinical trial designed to evaluate the	
11 12 13 14 15 16 17 18	Q. Have you ever been involved in the clinical trial designed to evaluate the safety and efficacy of a medical device? When I say clinical trial, I mean in humans. A. Yes. Q. What was that? A. 1998 to '99, it was a new design		12 13 14 15 16 17 18	clinical trial designed to evaluate the safety and efficacy of a prolapse device; correct? A. Correct. Q. You've never been involved in a clinical trial designed to evaluate the safety and efficacy of a stress urinary	
11 12 13 14 15 16 17 18 19	Q. Have you ever been involved in the clinical trial designed to evaluate the safety and efficacy of a medical device? When I say clinical trial, I mean in humans. A. Yes. Q. What was that? A. 1998 to '99, it was a new design of an artificial urinary sphincter for men,		12 13 14 15 16 17 18 19	clinical trial designed to evaluate the safety and efficacy of a prolapse device; correct? A. Correct. Q. You've never been involved in a clinical trial designed to evaluate the safety and efficacy of a stress urinary incontinence synthetic sling; correct?	
11 12 13 14 15 16 17 18 19 20	Q. Have you ever been involved in the clinical trial designed to evaluate the safety and efficacy of a medical device? When I say clinical trial, I mean in humans. A. Yes. Q. What was that? A. 1998 to '99, it was a new design of an artificial urinary sphincter for men, and I was involved in the original dog		12 13 14 15 16 17 18 19 20	clinical trial designed to evaluate the safety and efficacy of a prolapse device; correct? A. Correct. Q. You've never been involved in a clinical trial designed to evaluate the safety and efficacy of a stress urinary incontinence synthetic sling; correct? A. Correct. I have not.	
11 12 13 14 15 16 17 18 19 20 21	Q. Have you ever been involved in the clinical trial designed to evaluate the safety and efficacy of a medical device? When I say clinical trial, I mean in humans. A. Yes. Q. What was that? A. 1998 to '99, it was a new design of an artificial urinary sphincter for men, and I was involved in the original dog studies and then it went into human trials,		12 13 14 15 16 17 18 19 20 21	clinical trial designed to evaluate the safety and efficacy of a prolapse device; correct? A. Correct. Q. You've never been involved in a clinical trial designed to evaluate the safety and efficacy of a stress urinary incontinence synthetic sling; correct? A. Correct. I have not. MR. SNELL: Why don't we take a	
11 12 13 14 15 16 17 18 19 20 21 22	Q. Have you ever been involved in the clinical trial designed to evaluate the safety and efficacy of a medical device? When I say clinical trial, I mean in humans. A. Yes. Q. What was that? A. 1998 to '99, it was a new design of an artificial urinary sphincter for men, and I was involved in the original dog studies and then it went into human trials, which my name was on. However, I was not		12 13 14 15 16 17 18 19 20 21 22	clinical trial designed to evaluate the safety and efficacy of a prolapse device; correct? A. Correct. Q. You've never been involved in a clinical trial designed to evaluate the safety and efficacy of a stress urinary incontinence synthetic sling; correct? A. Correct. I have not. MR. SNELL: Why don't we take a break.	
11 12 13 14 15 16 17 18 19 20 21 22 23	Q. Have you ever been involved in the clinical trial designed to evaluate the safety and efficacy of a medical device? When I say clinical trial, I mean in humans. A. Yes. Q. What was that? A. 1998 to '99, it was a new design of an artificial urinary sphincter for men, and I was involved in the original dog studies and then it went into human trials, which my name was on. However, I was not involved because I went down to my		12 13 14 15 16 17 18 19 20 21 22 23	clinical trial designed to evaluate the safety and efficacy of a prolapse device; correct? A. Correct. Q. You've never been involved in a clinical trial designed to evaluate the safety and efficacy of a stress urinary incontinence synthetic sling; correct? A. Correct. I have not. MR. SNELL: Why don't we take a break. (Recess, 11:15-11:52 a.m.)	
11 12 13 14 15 16 17 18 19 20 21 22	Q. Have you ever been involved in the clinical trial designed to evaluate the safety and efficacy of a medical device? When I say clinical trial, I mean in humans. A. Yes. Q. What was that? A. 1998 to '99, it was a new design of an artificial urinary sphincter for men, and I was involved in the original dog studies and then it went into human trials, which my name was on. However, I was not		12 13 14 15 16 17 18 19 20 21 22	clinical trial designed to evaluate the safety and efficacy of a prolapse device; correct? A. Correct. Q. You've never been involved in a clinical trial designed to evaluate the safety and efficacy of a stress urinary incontinence synthetic sling; correct? A. Correct. I have not. MR. SNELL: Why don't we take a break.	

		Page 410			Page 411
1	involved in a clinical trial designed to	ū	1	Q. Doctor, I've handed you Exhibit	
2	assess the safety and efficacy of a stress		2	Number 9, which is the Iglesia randomized,	
3	urinary incontinence device; correct?		3	controlled trial in which you referred to	
	· · · · · · · · · · · · · · · · · · ·			•	
4	A. Correct.		4	yesterday; correct?	
5	Q. Prior to becoming involved in		5	A. Yes.	
6	this litigation, you had never reviewed a		6	Q. And you know that in this study	
7	device design safety assessment; correct?		7	only 65 women were ultimately recruited into	
8	A. From an industry, I guess I don't		8	the study; correct?	
9	know I just want to make sure I'm clear		9	A. That is correct.	
10	in understanding your question.		10	Q. And of those, there were 32 women	
11	Q. Yes.		11	who received mesh placement; correct?	
12	A. Would this be an industry		12	A. Yes.	
13	Q. From a manufacturer, yes.		13	Q. And the 32 women were recruited	
14	A. No, I have not.		14	between January 2007 to August 2009;	
15	Q. You're not an FDA regulatory		15	correct?	
16	expert, are you?		16	A. That is correct.	
17	A. No, I'm not.		17	Q. You mentioned the mesh exposures	
18	Q. Yesterday, Doctor, you mentioned		18	with this study yesterday in your testimony;	
19	the Iglesia study?		19	correct?	
20	A. Yes.		20	A. That is correct.	
	MR. SNELL: Can we mark it as				
21			21	Q. Turn, if you would, Doctor, to	
22	the next exhibit.		22	the bottom of Page 298.	
23	(Exhibit Elliott-9 was marked		23	A. (Witness complies.)	
24	for identification.)		24	Q. And do you see it says, "Of the	
25	BY MR. SNELL:		25	32 mesh patients, five developed erosions"?	
		Page 412			Page 413
1	Do you see that?	Page 412	1	where I'm I'm just seeing what their	Page 413
1 2	Do you see that? A. Yes.	Page 412	1 2	where I'm I'm just seeing what their treatment was. Yes, it does discuss that,	Page 413
	A. Yes.	Page 412			Page 413
2	A. Yes. Q. Now, this is something that we've	Page 412	2	treatment was. Yes, it does discuss that, what they did.	Page 413
2 3 4	A. Yes. Q. Now, this is something that we've discussed over the course of your	Page 412	2 3 4	treatment was. Yes, it does discuss that, what they did. Q. Three of them required a	Page 413
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Page 414 Page 415 1 each group had a febrile illness while 1 And one patient in the non-mesh 2 hospitalized, and that would usually mean 2 group had a febrile illness while you're going to have to -- you're going to 3 3 hospitalized; correct? 4 give antibiotics. So your question was --4 Α. That is correct. 5 Q. My question is, the authors 5 O. And the rate of febrile illness 6 report that none of the Prolift® patients 6 while hospitalized with Prolift® was not 7 had a major infection, requiring use of 7 higher than that with the non-mesh group; 8 8 postoperative antibiotics; correct? correct? 9 A. Major infection. Well, that's 9 A. Well, statistically speaking, it 10 what it says there but that's not congruent 10 was higher because there are 32 in mesh and 33 in the non-mesh so one patient in each, 11 with what they say, one patient in each 11 group had a febrile illness while statistically speaking, would be different. 12 12 But I know what you're saying. 13 hospitalized. 13 MR. SNELL: No. Move to 14 You don't get a fever unless 14 15 you have an infection. So I see what you're 15 strike. BY MR. SNELL: saying but I see incongruency in the data. 16 16 If I were reviewing this manuscript, I would 17 17 O. One patient in each group had a 18 say I need clarification. 18 febrile illness while hospitalized; correct? Q. Well, only one patient in the 19 A. That is correct, yes. 19 20 Prolift® group had a febrile illness while 20 Q. And there was 32 patients in one hospitalized; correct? 21 group and 33 patients in the other group; 21 A. That is correct. That's what 22 22 correct? 23 23 A. That is correct. they assess, yes. 24 Q. And only one patient in the 24 Q. And are you saying that there is 25 non-mesh group -- strike that. 25 a statistically significant difference Page 416 Page 417 between that one febrile illness in each 1 do it, the difference. 1 2 2 O. One in 33 is 33.33 repeating group? percent; correct? 3 A. What I'm saying is there is a 3 4 percentage, you're correct, not 4 A. Yes. 5 5 statistically significant, but there's a Q. One in 32 is 31.25; correct? 6 percentage difference just because one out 6 A. I'll take your word for it. 7 of 32 is different than one out of 33. 7 There's no statistically O. 8 8 MR. ANDERSON: You asked about significant difference reported between the rate of illness, not the number of 9 these febrile illnesses in the two cohorts; illnesses. That's what he was referring to. 10 correct? 10 MR. SNELL: Okay. They do not report it, no. 11 11 Α. 12 12 O. What are the reasons why a BY MR. SNELL: Q. The number of febrile illnesses patient would develop a febrile illness? 13 13 was not different for the Prolift® versus A. There will be many potential 14 14 15 the non-mesh group; correct? 15 reasons, so it's going to be difficult to A. Correct. Just because when I narrow it down to just a few. 16 16 review manuscripts, which I take a lot of It could be a complication of 17 17 18 pride in, and hence The Journal of Urology 18 surgery itself, bowel perforation, bladder awarded me the award as far as the best perforation, wound infection, rectal injury, 19 19 reviewer in female urology, that's why I 20 sigmoid injury, atelectasis, pulmonary 20 embolism, stroke. You know, there's a -just, when I hear words, I want to be more 21 21 22 specific about it. 22 there's an extensive list. Q. And the difference between one in 23 23 Q. Can you, as you look at this paper by Iglesia, Dr. Sokol and others, can 24 32 and one in 33 is what? 24 25 A. I'd have to get a calculator and you tell me, see the percentage of patients

	Page 418			Page 419
1	who developed mesh exposure was 15.6	1	would be terminated, and I would imagine	
2	percent; right?	2	that was established by an ethics committee.	
3	A. Yes.	3	Q. And as you look at this paper, do	
4	Q. And the study was stopped because	4	you know what the rate of erosion was in the	
5	the rate of mesh exposure was more than 15	5	non-mesh group?	
6	percent; correct?	6	A. In the non-mesh group? I would	
7	A. Yeah. Again, I'd have to look at	7	have to look through it. I don't I don't	
8	the paper specifically but	8	recall.	
9	Q. I'm on Page 302.	9	Q. Would you expect the rate of	
10	MR. ANDERSON: Right here	10	suture erosion to be reported in this study?	
11	(indicating).	11	A. Again, I would have to look at	
12	THE WITNESS: 302. Yeah.	12	the paper, see how they did their anterior	
13	BY MR. SNELL:	13	colporrhaphies or the prolapse repairs.	
14	Q. It says, "Weakness include the	14	Many surgeons, including	
15	short follow-up and lack of statistical	15	myself, do not use permanent sutures so	
16	power due to premature stopping as a result	16	erosion is or extrusion is not an issue.	
17	of reaching predetermined mesh erosion rates	17	I don't recall how they did their repairs.	
18	of more than 15%."	18	Q. If the rate of suture erosion was	
19	Do you see that, Doctor?	19	15 percent or more, would you expect it to	
20	A. Yes.	20		
21		21	be in this paper by Dr. Iglesia?	
	Q. So the study was stopped because		A. I think it should be reported,	
22	of the exposure rate of more than 15	22	yes. But I see the sutures they used in	
23	percent; correct?	23	here. They used absorbable oh, PDS.	
24	A. Yes. They had a they had a	24	Well, I don't know what size they used.	
25	predetermined threshold once crossed, it	25	PDS. That's what I use. And also they do	
	Page 420			Daga 421
1	Page 420	1	those who had recurrent prolance; correct?	Page 421
1	use polytetrafluoroethylene.	1	those who had recurrent prolapse; correct?	Page 421
2	use polytetrafluoroethylene. Q. Is that Gore-Tex?	2	A. Yes.	Page 421
2 3	use polytetrafluoroethylene. Q. Is that Gore-Tex? A. Yes. That's for their	2	A. Yes. Q. And ultimately, 97 women	Page 421
2 3 4	use polytetrafluoroethylene. Q. Is that Gore-Tex? A. Yes. That's for their culdoplasties, according to what they say	2 3 4	A. Yes. Q. And ultimately, 97 women underwent conventional repair and 93	Page 421
2 3 4 5	use polytetrafluoroethylene. Q. Is that Gore-Tex? A. Yes. That's for their culdoplasties, according to what they say here.	2 3 4 5	A. Yes. Q. And ultimately, 97 women underwent conventional repair and 93 underwent the Prolift® repair; correct?	Page 421
2 3 4 5 6	use polytetrafluoroethylene. Q. Is that Gore-Tex? A. Yes. That's for their culdoplasties, according to what they say here. Q. One of the other articles you	2 3 4 5 6	A. Yes. Q. And ultimately, 97 women underwent conventional repair and 93 underwent the Prolift® repair; correct? A. Yes.	Page 421
2 3 4 5 6 7	use polytetrafluoroethylene. Q. Is that Gore-Tex? A. Yes. That's for their culdoplasties, according to what they say here. Q. One of the other articles you mentioned yesterday was the Withagen paper;	2 3 4 5 6 7	A. Yes. Q. And ultimately, 97 women underwent conventional repair and 93 underwent the Prolift® repair; correct? A. Yes. Q. And there was a 98 percent	Page 421
2 3 4 5 6 7 8	use polytetrafluoroethylene. Q. Is that Gore-Tex? A. Yes. That's for their culdoplasties, according to what they say here. Q. One of the other articles you mentioned yesterday was the Withagen paper; correct, Doctor?	2 3 4 5 6 7 8	A. Yes. Q. And ultimately, 97 women underwent conventional repair and 93 underwent the Prolift® repair; correct? A. Yes. Q. And there was a 98 percent follow-up rate at one year; correct?	Page 421
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	•	Page 422			Page 423
1	Q. And that difference was		1	the vaginal mesh Prolift® group had a lower	
2	statistically significant; correct?		2	rate of POPQ failure; correct?	
3	 A. It's a very significant anatomic 		3	A. Correct.	
4	difference, yes.		4	Q. And in all patients at 12 months	
5	Q. Turn, if you would, Doctor, to		5	there was a lower rate of POPQ failure at 12	
6	Page 247. And I'm on the left column in the		6	months; correct?	
7	text. Let me know whenever you're ready.		7	A. Yeah. Correct.	
8	A. Left. Yeah. Uh-huh.		8	Q. I think I said that twice. Let	
9	Q. On Page 247 the study authors		9	me just back up.	
10	report, in the conventional group failure		10	In all patients at 12 months	
11	rates were higher in both anterior as well		11	there was a lower rate of POPQ failure in	
12	as in the posterior compartment compared		12	the Prolift® group compared to the	
13	with the tension-free vaginal mesh group,		13	conventional group; correct?	
14	citing Table 5; correct?		14	A. That is correct.	
15	A. That is correct. They were		15	Q. And for those patients undergoing	
16	referring to anatomic failure.		16	anterior compartment repair at six months	
17	Q. Correct. And if we look at Table		17	there was a lower rate of POPQ failure for	
18	5, where they're looking at POPQ stage two		18	the Prolift® group as compared to the	
19	or greater failure; correct?		19 20	conventional group; correct? A. Correct.	
20	A. They don't say POPQ. I would		21		
21 22	assume they would have used POPQ, though. I'd have to go to Table where they refer	•	22	Q. And at 12 months for those patients undergoing anterior repair there	
23	to Table 5. For it to have gotten published		23	was a lower rate of POPQ failure with the	
24	in 2011, it has to be POPQ.		23 24	Prolift® group compared to the conventional	
25	Q. So in all patients at six months		25	group; correct?	
23	Q. 50 III dii padents at six months		3	group, correct:	
		Page 424			Page 425
1	A. Correct.	Page 424	1	significant difference; correct?	Page 425
1 2	A. Correct. O. At one year in the anterior	Page 424	1 2	significant difference; correct? A. No. They had equal results.	Page 425
2	Q. At one year in the anterior	Page 424	2	A. No. They had equal results,	Page 425
2 3	Q. At one year in the anterior compartment cohort there were 7.8 percent	Page 424		A. No. They had equal results, anatomic, POPQ.	Page 425
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2 3 4	Q. At one year in the anterior compartment cohort there were 7.8 percent POPQ failures in the Prolift® group;	Page 424	2 3 4	A. No. They had equal results, anatomic, POPQ. Q. Why don't we look at Table 3.	Page 425
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		Page 426			Page 427
1	have to also look at the patient in		1	record.	
2	totality. Anatomy alone is not sufficient.		2	(Discussion off the record.)	
3	MR. SNELL: Objection. Move to		3	BY MR. SNELL:	
4	strike.		4	Q. Doctor, I believe you earlier	
5	MR. ANDERSON: He didn't		5	testified that before you became involved in	
6	MR. SNELL: I don't have a		6	this litigation, you had not looked at any	
7	question pending.		7	pathology slides of mesh; correct?	
8	MR. ANDERSON: He doesn't want		8	A. I've seen, well, gross	
9	to ask you about that.		9	photographic specimens from patients that I	
10	THE WITNESS: I was continuing		10	have explanted. But pathology study, you	
11	to think.		11	mean microscopic slides, is that what you're	
12	MR. ANDERSON: He doesn't		12	referring to?	
13	THE WITNESS: I'm not supposed		13	Q. Yes.	
14	to think anymore?		14	A. Probably at lectures. But it	
15	MR. SNELL: You're here to		15	•	
				would be fairly limited.	
16	answer my questions. I know you have your		16	Q. Yesterday you recall two patients	
17	opinions and prerogative, and I hear you.		17	for Prolift® for whom you had treated for	
18	THE WITNESS: Understood.		18	complications; correct?	
19	BY MR. SNELL:		19	A. Correct.	
20	Q. Since you did bring up		20	Q. And in your treatment of those	
21	symptomatic, in the Withagen paper there		21	patients you did not see degradation of the	
22	were symptomatic improvements in the		22	mesh, did you?	
23	Prolift® group; correct?		23	A. Well, what I'm describing as far	
24	A. Absolutely. Roughly 80 percent.		24	as degradation, I don't know if these are	
25	MR. SNELL: Let's go off the		25	extrusion individuals. In those	
		D 420			D 420
1	individuals I mean I can't recall	Page 428	1	Prolift®: correct?	Page 429
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2	specifically.	Page 428	2	A. Well, I would have to look at the	
2	specifically. What I'm referring to as	Page 428	2	A. Well, I would have to look at the manuscript to know which products were use	
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	Page 430			Page 431
1	Q you don't know how many, if	1	residents, you have to look and feel for the	
2	any, of those 100 explants in that study	2	mesh. And many times, it's so encased in	
3	were Prolift®; correct?	3	scar that you have to go by feel, then you	
4	A. No, I don't. From my knowledge,	4	can feel the poking sensation of it. It's	
5	all I know is they were polypropylene. I'd	5	sharp.	
6	have to review the manuscript to determine	6	Q. And in the Prolift® mesh that you	
7	•	7	-	
	that.		have examined, you don't recall it being	
8	Q. The barbed-wire effect that you	8	barbed wire; correct?	
9	note on Page 58	9	A. No. I cannot recall. I did not	
10	A. Yes.	10	keep records if it was specifically	
11	Q that is a quote from	11	Prolift®. I do know specifically TVT® but	
12	Dr. Klinge; correct?	12	not Prolift®.	
13	A. Actually, I don't know if that's	13	Q. Can you tell me any clinical	
14	his or mine, because I felt that. So I	14	human studies in TVT® that reported a	
15	would have to if I give a reference, 88.	15	barbed-wire effect with the mesh?	
16	I don't know if Dr. Klinge said it. I I	16	A. I don't recall off the top of my	
17	don't recall when I wrote this if I was	17	head, no. Barbed wire is a descriptive	
18	quoting, just making the putting aside	18	term, not a scientific term.	
19	because that's what I have felt. He may	19	MR. SNELL: Okay. Let's have	
20	have said the same thing also.	20	some lunch.	
21	Q. When you say that is what you had	21	(Luncheon recess,	
22	felt, what do you mean by that?	22	12:29-1:15 p.m.)	
23	A. Meaning when I've taken explants	23	AFTERNOON SESSION	
24	of mesh material, it's this friable, broken,	24	BY MR. SNELL:	
25	you can that's why when I instruct the	25	Q. Am I correct that you never	
	p 400			
١,	Page 432	_	2 7 1 1 1 1 1 1	Page 433
1	looked at any FDA guidance documents before	1	Q. You're not a regulatory expert on	Page 433
2	looked at any FDA guidance documents before becoming involved in this litigation?	2	510(k) clearance.	Page 433
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				1
	Page 434			Page 435
1	Mrs. Gross; correct?	1	A. That is correct.	
2	MR. ANDERSON: Objection.	2	Q. When did you receive the medical	
3	Asked and answered.	3	records of Linda Gross?	
4	Go ahead.	4	A. I don't recall exact date.	
5	THE WITNESS: Correct.	5	Q. Give me your best approximation	
6	BY MR. SNELL:	6	under oath.	
7	Q. And the opinions you offer in	7	MR. ANDERSON: Objection.	
8	this report consist of one paragraph with	8	THE WITNESS: November 7th. I	
9	regard to Mrs. Gross; correct?	9	would this is a very rough guess because	
	•		,	
10	A. Well, two paragraphs in which her	10	there was a flood of information coming to	
11	name is mentioned, one paragraph specific to	11	me. Roughly a month prior to this.	
12	her.	12	BY MR. SNELL:	
13	Q. There's one paragraph where you	13	Q. Now, you haven't reviewed all of	
14	set forth opinions with regard to	14	Mrs. Gross's records; correct?	
15	Mrs. Gross; correct?	15	 A. I have reviewed, covered the 	
16	A. Yes.	16	medical records and I believe there's	
17	Q. And you referred I'm sorry.	17	depositions pertaining specifically to her	
18	Let me start over.	18	that I've reviewed, so I can't say if I've	
19	And you reviewed certain	19	read all because I don't know I don't	
20	medical records of Linda Gross, as	20	know what I don't know.	
21	identified in this report?	21	Q. So you don't know if this is a	
22	A. That is correct.	22	complete list of all of the records by Linda	
23	Q. These were medical records of	23	Gross; correct?	
24	Linda Gross that were given to you by	24	A. What I can state	
25	plaintiffs' counsel; correct?	25	MR. ANDERSON: Objection.	
23	plantents coursely correct.	2	The Anderson Objection	
	Page 436			Page 437
1	Go ahead.			· ·
		1	if there are other records out there.	
		1 2	if there are other records out there. O. Did you ask to look at all of	
2	THE WITNESS: What I can state	2	Q. Did you ask to look at all of	
2	THE WITNESS: What I can state is what is on here is what I've reviewed.	2 3	Q. Did you ask to look at all of Pamela Wicker's records?	
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Page 438 Page 439 A. Females. And then it depends 1 Q. Did you ask to examine 1 2 Mrs. Wicker? 2 upon the history as far as what they are presenting with, i.e., idiopathic 3 A. No. 3 4 4 symptomatology versus a causative factor. Q. Did you conduct any independent 5 testing on Mrs. Gross? 5 That's going to direct me if they've had 6 A. No. 6 surgery or not, what type of surgery they've 7 Q. Did you ask to conduct any 7 had, also, the severity of the problem. 8 independent testing on Mrs. Gross? 8 Then laboratory testing, 9 9 urinalysis would affect the evaluations, A. No. past evaluations that have been done, the 10 Did you conduct any independent 10 11 testing on Mrs. Wicker? 11 quality of the testing that had been done A. No. 12 12 elsewhere, if any. Did you ask to conduct any So I can't give you a simple 13 13 Q. independent testing on Mrs. Wicker? answer because there's so many variables 14 14 that go into the equation. 15 A. No. 15 Q. Are there certain urinary tests 16 Q. If a patient has urinary 16 dysfunction, what are the tests that you that can be done to help determine the 17 17 18 perform to come to that conclusion? 18 etiology of urinary dysfunction? 19 A. Depends upon the symptoms. 19 A. Yes. 20 Q. Can you tell me the tests and the 20 What might those be, Doctor? O. symptoms that would lead you to conduct such 21 A. Screening uroflow or post void 21 residual check. That would just be an 22 a test? 22 ultrasound to see if the bladder is elevated 23 A. Well, it, number one, depends if 23 capacity -- excuse me -- elevated residual 24 it's a male or a female. 24 or does the bladder empty out or somewhere 25 Q. Let's only focus on females. 25 Page 440 Page 441 in between. 1 ultrasound. Possibly a CAT scan of the 1 abdomen and kidneys versus possibly an MRI. 2 The flow rate, how fast the 2 urine can come out, the pattern on the flow 3 I think that's pretty much it. 3 rate, is the woman straining or does it Q. And in your report regarding 4 4 5 appear to be a bladder contraction type of a 5 Mrs. Gross did you identify any testing that 6 flow? was done on Mrs. Gross with respect to her 6 7 7 urinary retention or dysfunction at any Another study could be a 8 8 urodynamics that looks at the function of time? the bladder, spelled U-R-O-D-Y-N-A-M-I-C-S, 9 Α. Yeah. I'd have to go back and 10 urodynamics, or cystometrogram is another 10 look at specifically all that was done. It 11 was fresh in my mind when I wrote the report term. 11 but I do recall, as I recall, there was a 12 Again, that depends upon 12 multiple different factors of what got the residual urine check, there may or may not 13 13 patient to see me. It's a fairly expensive have been cystoscopies. Again, for 14 14 15 study so I don't order them on everybody. 15 specifics for each individual, I'd have to And that evaluates the bladder, how much the check on that and look at the records again. 16 16 patient can hold, the sensation levels, the Q. Well, you didn't put the results 17 17 18 -- their bladder spasms, bladder pain with 18 of any residual urine check in your report; filling. Then during the urination phase, 19 19 correct? is the bladder working or not to get the 20 A. That is correct. 20 urine out? How much is left behind? You didn't put the results of any 21 21 Q. cystoscopy in your report; correct? 22 Other studies can be cystoscopy 22

23

24

25

Q.

A. Yes -- well, yes, there is.

Where is that, Doctor?

Mrs. Gross, last sentence, "I

but, again, there has to be a reason why I'm

going to do that. Other studies, possibly

pelvic ultrasound versus transvaginal

23

24

25

	•	Page 442			Page 443
1	also note that the findings seen by	-	1	MR. ANDERSON: Okay.	
2	Dr. Benson on cystoscopy were not		2	MR. SNELL: based upon what	
3	'interstitial cystitis.'"		3	he reviewed and what he did or did not put	
4	Q. So other than the cystoscopy, you		4	in his report.	
5	did not identify any other testing that		5	THE WITNESS: As I sit here,	
6	Mrs. Gross had undergone.		6	going by memory, I cannot recall the	
7	A. I do not		7	specific studies that were done on her.	
8	Q. Correct?		8	BY MR. SNELL:	
9			9	Q. You reference the sentence where	
	·			<u> </u>	
10	Q. As you sit here today, do you		10	you opine that the findings seen by	
11	recall the results of any urodynamic studies		11	Dr. Benson on cystoscopy were not	
12	on Mrs. Gross?		12	interstitial cystitis but, rather, due to	
13	A. I do not recall.		13	urinary retention and irritation of the	
14	Q. Do you know whether urodynamic		14	bladder by the Prolift® mesh.	
15	studies were even done on Mrs. Gross?		15	Do you see that?	
16	 At this point in time right now, 		16	A. That's correct.	
17	I cannot recall.		17	Q. What's your basis for that	
18	Q. Do you know the pattern on		18	statement?	
19	Mrs. Gross's flow rate, if any such testing		19	 A. Well, with cystoscopy there are 	
20	was performed?		20	no pathognomonic findings for interstitial	
21	MR. ANDERSON: Are you just		21	cystitis to the point that cystoscopies are	
22	asking from memory or do you want him to		22	not recommended in interstitial cystitis.	
23	look at records?		23	Any findings within the bladder	
24	MR. SNELL: I'm asking him as		24	are not consistent to rule out or include,	
25	he sits here and recalls		25	and by exclusion, interstitial cystitis	
		Page 444			Page 445
1	cannot have any other concurrent pathology	Page 444	1	Pertaining to Mrs. Wicker in	Page 445
1 2	cannot have any other concurrent pathology in the pelvis and bladder, so the findings,	Page 444	1 2	Pertaining to Mrs. Wicker in the deposition by Dr. Raz, it says my	Page 445
2	in the pelvis and bladder, so the findings,	Page 444	2	the deposition by Dr. Raz, it says my	Page 445
2	in the pelvis and bladder, so the findings, based upon that, were consistent with the	Page 444	2 3	the deposition by Dr. Raz, it says my opinion and his are the same. So I can rule	Page 445
2 3 4	in the pelvis and bladder, so the findings, based upon that, were consistent with the irritation and previous surgeries and the	Page 444	2 3 4	the deposition by Dr. Raz, it says my opinion and his are the same. So I can rule out interstitial cystitis.	Page 445
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1	criteria. So that is not decided by one		1	Interstitial cystitis is a	
2	person; it's a consortium.		2	diagnosis of exclusion. What that means is	
3	Q. And what are the diagnostic		3	you rule out everything else and if you	
4	criteria for interstitial cystitis?		4	can't find anything and they meet the pain	
5	A. I would need that paper to be		5	symptom criteria, pain with filling,	
6	thorough, so if we have that paper, that		6	relieved by urination are the classic ones,	
7 8	would be the best.		7	then that's interstitial cystitis because	
	From memory, you have specific		8	there is no biopsy, there is no cystoscopy,	
9	bladder pain with filling, tends to be		9 10	there is no imaging that used in the diagnosis of IC.	
10 11	relieved by urination, you do not have generalized pelvic pain, acute onset of		11	Q. What objective testing on	
12	urgency to urinate with leakage usually		12	Mrs. Gross's case showed irritation of the	
13	rules out IC. Those are off the top of my		13	bladder by the Prolift® mesh?	
14	head. The paper is much more thorough.		14	A. Well, that's the cystoscopy.	
15	Q. The statement where you make that		15	Q. Did the cystoscopy report that	
16	one cannot have interstitial cystitis if		16	there was Prolift® mesh in the bladder?	
17	other concurrent pathology is present, what		17	A. I don't recall. I'd have to look	
18	do you mean by other concurrent pathology?		18	at it. But I do not recall erosion being a	
19	A. Meaning an etiology for bladder		19	factor, no.	
20	dysfunction.		20	Q. What objective testing showed	
21	Q. Can you explain that in laymen's		21	urinary retention by the Prolift® mesh?	
22	terms?		22	A. Well, I mean, an elevated	
23	A. Like an example would be a		23	residual urine.	
24	urinary tract infection, surgery, trauma,		24	Q. Is an elevated residual urine a	
25	something else that can be causing it.		25	finding that's specific to Prolift® mesh or	
		Page 448			Page 449
1	can that be from other causes?	Page 448	1	A. Off the top of my head, no.	Page 449
2	A. There can be other causes.	Page 448	2	Q. How is injury to the pelvic	Page 449
2 3	A. There can be other causes.Q. Can an irritation of the bladder	Page 448	2 3	Q. How is injury to the pelvic neuroanatomy objectively diagnosed?	Page 449
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		Page 450			Page 451
1	say.		1	Q. And as you do you plan to	
2	Q. Did Mrs. Gross undergo		2	offer an opinion at trial as to whether	
3	urodynamics?		3	Prolift® was an appropriate surgical option	
4	A. Either Miss Gross or Miss Wicker		4	to offer to Mrs. Gross by her doctors?	
5	did. I cannot recall off the top of my		5	A. No. I was instructed, was	
6	head. I'd have to look at the records		6	Prolift® a causative factor in the voiding	
7	again.		7	dysfunction, not whether or not the Prolift®	
8	-		8	was the correct treatment or not.	
			_		
9	problems before her Prolift® implantation?		9	Q. So the only opinions you plan to	
10	A. Again, I'd have to go back to the		10	offer at trial is in connection with the	
11	records to review that because I can't		11	analysis of was Prolift® a causative factor	
12	recall.		12	in any urinary problems with Mrs. Gross.	
13	Q. You know that she had a long		13	And I'm talking about opinions specific to	
14	history of stress urinary incontinence.		14	the Gross case.	
15	 A. Again, I'd have to go back to the 		15	A. Sure. I understand.	
16	records and		16	Q. Is that correct or not?	
17	MR. ANDERSON: I'm happy to go		17	MR. ANDERSON: Objection.	
18	to try to grab any record that you would		18	Go ahead.	
19	like for him to refer to, Burt. Counsel.		19	THE WITNESS: Well, unless	
20	BY MR. SNELL:		20	somebody asks me, was it the correct thing?	
21	Q. You did not in your expert report		21	But I'm not volunteering that information.	
22	regarding Mrs. Gross state an opinion about		22	Because my understanding when asked to	
23	whether Prolift® was a proper surgical		23	review Gross and Wicker, it was specifically	
24	option to offer by her surgeon, did you?		24	what caused their voiding dysfunction.	
25	A. That is correct. I did not.		25	BY MR. SNELL:	
23	A. That is correct. I did not.		23	DT MR. SINLLL.	
		Page 452			Page 453
1	O. In your report regarding	Page 452	1	don't plan to come out and start talking	Page 453
1 2	Q. In your report regarding Mrs. Gross and Mrs. Wicker you have not	Page 452	1 2	don't plan to come out and start talking	Page 453
2	Mrs. Gross and Mrs. Wicker you have not	Page 452	2	about things that Mrs. Gross's doctors did	Page 453
2	Mrs. Gross and Mrs. Wicker you have not identified any criticism that you have with	Page 452	2 3	about things that Mrs. Gross's doctors did incorrectly.	Page 453
2 3 4	Mrs. Gross and Mrs. Wicker you have not identified any criticism that you have with regard to her doctors; correct?	Page 452	2 3 4	about things that Mrs. Gross's doctors did incorrectly. A. From what I understand, just so	Page 453
2 3 4 5	Mrs. Gross and Mrs. Wicker you have not identified any criticism that you have with regard to her doctors; correct? A. Correct.	Page 452	2 3 4 5	about things that Mrs. Gross's doctors did incorrectly. A. From what I understand, just so we're very, very clear, my opinion on Gross	Page 453
2 3 4 5 6	Mrs. Gross and Mrs. Wicker you have not identified any criticism that you have with regard to her doctors; correct? A. Correct. Q. And you don't plan to offer at	Page 452	2 3 4 5 6	about things that Mrs. Gross's doctors did incorrectly. A. From what I understand, just so we're very, very clear, my opinion on Gross and Wicker as outlined in here is	Page 453
2 3 4 5 6 7	Mrs. Gross and Mrs. Wicker you have not identified any criticism that you have with regard to her doctors; correct? A. Correct. Q. And you don't plan to offer at trial any criticisms about treatment	Page 452	2 3 4 5 6 7	about things that Mrs. Gross's doctors did incorrectly. A. From what I understand, just so we're very, very clear, my opinion on Gross and Wicker as outlined in here is specifically to their voiding dysfunction	Page 453
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		I			
	Pag	e 454			Page 455
1	dysfunction that Mrs. Gross and Mrs. Wicker		1	by the Prolift® I'm just going to read	
2	has, according to his opinions, and the		2	the whole sentence.	
3	cause thereof.		3	A. Yes, I see it.	
4	MR. ANDERSON: And voiding		4	Q. You state, "The injuries caused	
5	dysfunction encompasses a number of things,		5	by the Prolift are appear to be permanent";	
6	pelvic neuroanatomy, damage to that area, a		6	correct?	
7	number of things that you can ask him about		7	A. Yeah. That's an error. It	
			-		
8	in terms of exploring his opinions as to		8	should say the injuries caused by Prolift®	
9	what is related to that general opinion of		9	appear to be permanent. That "are," A-R-E,	
10	voiding dysfunction or pelvic sustained		10	should not be there.	
11	injury to the pelvic neuroanatomy or		11	Q. When you say the injuries caused	
12	neurologic function, et cetera.		12	by Prolift® appear to be permanent, are you	
13	But I think you're homing in on		13	talking about her voiding dysfunction?	
14	the area in which we've asked him or will		14	 A. I'm talking about the the 	
15	ask him to opine.		15	pain, pelvic floor myalgia	
16	BY MR. SNELL:		16	Q. Hold on.	
17	Q. Urinary dysfunction can be a		17	A and voiding dysfunction.	
18	potential complication of numerous prolapse		18	Q. When you say the pain, what pain	
19	surgeries other than Prolift®; correct?		19	are you referring to?	
20	A. Yes.		20	A. Pelvic pain.	
21	Q. Persistent pain is a potential		21	Q. Is this pelvic pain specifically	
22	• •		22		
	complication with other prolapse surgeries			associated with voiding dysfunction?	
23	besides Prolift®; correct?		23	A. Can be.	
24	A. Yes.		24	Q. In Mrs. Gross's case, I'm asking	
25	Q. When you say the injuries caused		25	you, is this pelvic pain you're discussing	
		e 456			Page 457
1	specifically tied to her voiding dysfunction	e 456	1	subject, pelvic pain, in Mrs. Gross?	Page 457
2	specifically tied to her voiding dysfunction or is this pelvic pain like one can see with	e 456	2	A. I believe I read that, yes.	Page 457
	specifically tied to her voiding dysfunction or is this pelvic pain like one can see with other forms of prolapse surgery?	e 456		A. I believe I read that, yes.Q. You know Dr. Margolis opines on	Page 457
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1	A. I know in reviewing the records,		1	this deposition, have you formed an opinion	
2	specifically the Mayo records and		2	to a reasonable degree of medical certainty	
3	Dr. Trabucco, that it was offered at Mayo.		3	whether the surgery was a causative factor	
4	Q. What opinions are you going to		4	in pelvic floor myalgia?	
5	offer about her pelvic floor strike that.		5	A. From my recollection of the	
6	What opinions are you going to		6	records, she did not have significant or any	
7	offer about Mrs. Gross's pelvic floor		7	pelvic floor myalgia preoperatively. Again,	
8	myalgia?		8	I'd have to review the records for that to	
9	A. Depends upon the question I'm		9	make sure. And from my recollection, it all	
10	asked.		10	began after surgery.	
11	Q. Well, I want to know what you're		11 12	MR. ANDERSON: And, again, I'll	
12	going to offer because all I have is one		13	offer to get whatever record that you would	
13 14	paragraph, Doctor. So tell me. A. Well, that I have to look at the		14	like for me to try to get in the room next	
15	chronology of her pelvic floor myalgia. Did		15	door, Counsel. (Discussion off the record.)	
16			16	BY MR. SNELL:	
17	she have it preop versus postop? If there were evidence that she had pelvic floor		17	Q. Do you have any opinions on how	
18	myalgia preop and it continued in the same		18	Mrs. Gross's pelvic pain should be treated?	
19	intensity postop, then surgery was not a		19	A. Having seen these patients	
20	causative factor.		20	extensively, this is a very difficult	
21	If she had no pelvic floor		21	situation.	
22	myalgia preop, then postop at some point in		22	My review of Dr. Trabucco's	
23	time developed severe pelvic floor myalgia,		23	management of the patient appears to be	
24	then I have a causative factor.		24	appropriate and I don't have any further	
25	Q. As you sit here today, Doctor, in		25	ways of altering the situation.	
	C - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1		_	3	
		Page 460			Page 461
1	Q. With regard to Mrs. Gross's	Page 460	1	And then they will either have	Page 461
2	pelvic floor myalgia, do you have any	Page 460	2	And then they will either have a one-week intensive therapy sessions, which	Page 461
2 3	pelvic floor myalgia, do you have any opinions on how that should be treated?	Page 460	2	And then they will either have a one-week intensive therapy sessions, which usually they don't do, more likely it's	Page 461
2 3 4	pelvic floor myalgia, do you have any opinions on how that should be treated? A. I personally send these patients	Page 460	2 3 4	And then they will either have a one-week intensive therapy sessions, which usually they don't do, more likely it's usually spread out over eight weeks, it's	Page 461
2 3 4 5	pelvic floor myalgia, do you have any opinions on how that should be treated? A. I personally send these patients to a physical medicine and rehab for pelvic	Page 460	2 3 4 5	And then they will either have a one-week intensive therapy sessions, which usually they don't do, more likely it's usually spread out over eight weeks, it's one treatment a week, hence, the reason why	Page 461
2 3 4 5 6	pelvic floor myalgia, do you have any opinions on how that should be treated? A. I personally send these patients to a physical medicine and rehab for pelvic we have a pelvic floor myalgia clinic.	Page 460	2 3 4 5 6	And then they will either have a one-week intensive therapy sessions, which usually they don't do, more likely it's usually spread out over eight weeks, it's one treatment a week, hence, the reason why it's difficult for people from a long ways	Page 461
2 3 4 5 6 7	pelvic floor myalgia, do you have any opinions on how that should be treated? A. I personally send these patients to a physical medicine and rehab for pelvic we have a pelvic floor myalgia clinic. Q. And that's a pelvic floor myalgia	Page 460	2 3 4 5 6 7	And then they will either have a one-week intensive therapy sessions, which usually they don't do, more likely it's usually spread out over eight weeks, it's one treatment a week, hence, the reason why it's difficult for people from a long ways away to stay.	Page 461
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Page 462 Page 463 Gross's voiding dysfunction will not improve 1 can improve over time; correct? 1 2 A. It depends upon the surgery. 2 over time? Radical hysterectomy, colon surgery, it does 3 3 A. Can I rule out will not improve? 4 not improve over time. Smaller surgeries, 4 Is that the same way as saying it's ves, there's a chance. So, again, I have to 5 5 permanent or can I -- I guess I don't be specific. I'm not trying to be 6 understand your --6 7 difficult. I have to be specific to the 7 MR. ANDERSON: Vernacular. 8 8 MR. SNELL: Yeah. That's fair. cause. 9 9 BY MR. SNELL: Q. Post prolapse surgery voiding 10 dysfunction can improve over time; correct? 10 Q. You would agree that Linda 11 A. Again, it depends upon the 11 Gross's voiding dysfunction may at some point down the road get better. 12 surgery because prolapse surgery encompasses 12 A. Again, correct. And that's why I a lot of different types of surgeries. So 13 13 native, non-mesh, yes, I've seen that put the word "appear" or "appears" to be 14 14 recover. I've also seen it not recover. permanent. But no, I cannot prove it will 15 15 not at some point in time improve. We don't 16 Sacrocolpopexy, usually I don't 16 see voiding dysfunction. And I don't have have that long-term data yet. 17 17 18 enough long-term experience to see what will 18 Q. And does she need to happen with mesh long term. self-catheterize currently? 19 19 20 Q. Can voiding dysfunction following 20 A. I don't know her current status. 21 a mesh prolapse surgery improve over time? 21 Q. You would agree that at some point in the future with further treatment 22 A. Specific transvaginal mesh? 22 Q. Yes. 23 23 and the passage of time, she may not need to 24 A. I suppose it could. 24 self-catheterize; correct? 25 Can you rule out that Linda 25 A. Again, depends upon the etiology. Q. Page 464 Page 465 If the etiology is disruption of the vaginal 1 nerves on top of the vagina extending to the 1 2 2 plexus, pelvic splanchnics, due to a bladder that include the sympathetic and 3 degradation or inflammation, it will not. 3 parasympathetic nervous system. So if those were disrupted, cut or injured in any way, 4 If those nerves are still 4 5 intact and the insult is removed, then there 5 it is most likely it will be a permanent is the chance with time it will improve. I 6 condition. 6 7 7 don't know that data and nobody knows that O. Were those nerves disrupted? And 8 8 data yet. if so, what's the testing or data that 9 Q. As you sit here today -- let me 9 showed that? 10 say, in your report you did not state that 10 A. She has a bladder that does not you believe to a reasonable degree of work. The only nerves that create bladder 11 11 12 medical certainty that there was a function is the vaginal plexus. So if the 12 13 disruption to the vaginal plexus and 13 vaginal plexus, you know, if they are cut, splanchnic nerve that you just said; the bladder won't work. So I guess your 14 14 15 correct? 15 question was -- what was your question? A. I did not state in my report --MR. ANDERSON: He wanted to 16 16 well, yeah, actually, I did. I said 17 17 know if disrupted was the first part. 18 including the --18 THE WITNESS: Oh, okay. Were those nerves disrupted. We have evidence of 19 Q. Where is it? 19 20 A. The first line, I said -- it says a bladder that does not work, we have a mesh 20 with -- starts "with regard" and then it 21 21 -- excuse me. We have a dissection in the 22 goes, you know, then the comma and the 22 region where those nerves are. We have a second says, "including injury to the pelvic 23 23 mesh that was put in. neuroanatomy." So that is what I said. 24 24 We have a mesh that was 25 The vaginal plexus is the 25 multiply operated on and she has a bladder

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1	that does not work, so I have a lot of		1	Q. Are there different degrees of	
2	evidence pointing towards the fact that		2	urinary retention?	
3	those nerves have been injured. If those		3	A. Yes.	
4	nerves were perfectly intact, she would be		4	Q. Can you tell me from a medical	
5	able to urinate.		5	standpoint what those degrees are?	
6	BY MR. SNELL:		6	A. Well, there's no not a defined	
7	Q. I think we got off on this		7	but we can have an individual who cannot	
8	tangent when I asked you about your opinion		8	empty their bladder at all to individuals	_
9	regarding the need to self-catheterize. I'm		9	who empty, you know, a certain percentage of	
10	just trying to understand it because this is		10	their urine.	
11	complex.		11	Q. Is there any recognized gradation	
12	A. Neuroanatomy is very complicated.		12	of the degree of retention associated with	
13	Q. Is it correct that at some point		13	voiding dysfunction?	
14	in the future Mrs. Gross may not need to		14	A. No. Technically, anything over	
15	self-catheterize?		15	100 milliliters is elevated, and there's no	
16	A. That is a possibility, yes.		16	gradation beyond that.	
17	Q. Is it correct that she may only		17	Q. Interstitial cystitis, what	
18	need to self-catheterize in the future on an		18	symptomatology can that condition manifest	
19	intermittent basis?		19	itself in?	
20	A. Yes, that is a possibility.		20	A. Bladder pain with filling.	
21	Q. And the self-catheterization is		21 22	Q. When you say with filling, what	
22	related to the voiding dysfunction; correct?		23	do you mean by that?	
23	A. That is to treat the voiding			A. That the bladder when empty or	
24 25	dysfunction, which her specific voiding dysfunction is retention.		24 25	following urination, the pain is relieved or markedly subsides and then as the bladder	
23	dysfurction is retention.		23	markedly subsides and then as the bladder	
	Pac	je 468			Page 469
1	fills up, as it stretches, it hurts.	JC 100	1	have one paragraph in your report that	age 105
2	Q. Did you see that Dr. Weber opined		2	outlines your opinions; correct?	
3	on Mrs. Gross's urinary dysfunction?		3	A. Yes.	
4	A. You said Mrs. Gross?		4	Q. And it's your opinion that	
5	Q. Yes.		5	Mrs. Wicker has bladder pain?	
6	A. Yes.		6	A. Yes.	
7	Q. Did you see that Dr. Margolis		7	Q. Urinary frequency?	
8	opined on Mrs. Gross's urinary dysfunction?		8	A. Yes.	
9	A. Yes.		9	Q. And urinary urgency.	
10	Q. And you saw those opinions before		10	A. Yes.	
11	you finalized your November 7th, 2012,		11	Q. What's the difference between	
12	report; correct?		12	urinary frequency and urinary urgency?	
13	A. Correct.		13	A. Frequency is going frequently,	
14	Q. You saw that Dr. Weber and		14	just the sheer number of voids during the	
15	Margolis had issued opinions about		15	day. Urgency is the acute onset of needing	
16	Mrs. Gross's pelvic pain before you		16	to void. They're describing two separate	
	finalized your November 7th, 2012, report;		17	voiding issues.	
17			18	Q. How is urinary frequency	
18	correct?				
18 19	correct? A. Correct.		19	evaluated?	
18 19 20	correct? A. Correct. Q. You saw that Drs. Weber and		19 20	evaluated? A. Usually a voiding diary.	
18 19 20 21	correct? A. Correct. Q. You saw that Drs. Weber and Margolis issued opinions about Mrs. Gross's		19 20 21	evaluated? A. Usually a voiding diary. Q. Did you look at a voiding diary	
18 19 20 21 22	correct? A. Correct. Q. You saw that Drs. Weber and Margolis issued opinions about Mrs. Gross's pelvic floor myalgia before you completed		19 20 21 22	evaluated? A. Usually a voiding diary. Q. Did you look at a voiding diary for Mrs. Wicker?	
18 19 20 21 22 23	correct? A. Correct. Q. You saw that Drs. Weber and Margolis issued opinions about Mrs. Gross's pelvic floor myalgia before you completed your November 7th, 2012, report; correct?		19 20 21 22 23	evaluated? A. Usually a voiding diary. Q. Did you look at a voiding diary for Mrs. Wicker? A. I looked at somebody's voiding	
18 19 20 21 22 23 24	correct? A. Correct. Q. You saw that Drs. Weber and Margolis issued opinions about Mrs. Gross's pelvic floor myalgia before you completed your November 7th, 2012, report; correct? A. Correct.		19 20 21 22 23 24	evaluated? A. Usually a voiding diary. Q. Did you look at a voiding diary for Mrs. Wicker? A. I looked at somebody's voiding diary. I don't recall whose it was.	
18 19 20 21 22 23	correct? A. Correct. Q. You saw that Drs. Weber and Margolis issued opinions about Mrs. Gross's pelvic floor myalgia before you completed your November 7th, 2012, report; correct?		19 20 21 22 23	evaluated? A. Usually a voiding diary. Q. Did you look at a voiding diary for Mrs. Wicker? A. I looked at somebody's voiding	

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	Page 470			Page 471
1	coming to a diagnosis of urinary frequency?	1	However, if they've been in a	
2	A. Well, yeah. I think it may be a	2	meeting drinking Coke and coffee all day,	
3	combination of things: A urinalysis to rule	3	the frequency goes up. But, see, that's an	
4	out infection and the concentration of	4	aberrancy. That's why the voiding diary	
5	urine, the voiding diary to actually	5	looks at multiple days.	
6	document how frequent it actually is, and I	6	Q. The 400 to 600 milliliters you	
7	believe that would be it.	7	referenced, that's the normal bladder	
8	Q. Is there specific criteria for	8	capacity?	
9	diagnosing urinary frequency?	9	A. That's a range that is quoted as	
10	A. No, there's not a set number of	10	being somewhat consistent as being normal,	
11	voids per day. No.	11	yes.	
12	Q. Why is that?	12	Q. Is that in men or women or both?	
13	A. Well, there is going to be a	13	A. Both. And there will be	
14	variation in the frequency of the day that	14	acceptable ranges outside of that. So it's	
15	is within the realm of a range of normal.	15	not like it's clearly defined.	
16	It's like saying what's the appropriate foot	16	Q. For Mrs. Wicker, do you know how	
17	size or how tall what is the correct	17	her how big of a woman she is?	
18	height? That does not exist. There's a	18	A. No, I do not.	
19	range that's acceptable or normal.	19	Q. Do you know what's the size of	
20	And so urinary frequency, a	20	her particular bladder?	
21	normal bladder holds 400 to 600 milliliters.	21	A. I don't know. I'd have to look	
22	A normal person, on average, consumes one to	22	back at the records and see what Dr. Raz	
23	two liters of urine per fluid per day, so	23	said.	
24	subsequently they're going to void a certain	24	Q. And how is the size of a bladder	
25	number of times.	25	determined?	
23	number of times.	23	determined:	
	Page 472			Page 473
1	A. Well, if you performed a	1	Q. So if a woman drinks fluids	
2	urodynamics, you would know because you	2	frequently throughout the day, there will be	
3	would fill them up until they're full, or if	3	more urinary frequency; correct?	
4	you'd had what's called a uroflow where they	4	 A. But just drinking frequently, if 	
5	urinate into a container, you'd be able to	5	she's taking sips, that will not. You have	
6	know at least how much they could hold on	6	to look at that's why the voiding diary	
7	that event if they are full.	7	is basically the in and out of the day, how	
8	Q. Well, how do you know when	8	much in, fluid in, versus how much fluid	
9	they're full?	9	out.	
10	A. When they say I'm full. So you	10	So frequent drinking in and of	
11	cannot perform urodynamics or uroflow on	11	itself does not mean anything. If they're	
12	somebody who is cognitively impaired in any	12	drinking three liters of fluid a day and	
13	way. You're relying on the interaction of	13	they're not a marathon runner, that means	
14	the patient.	14	something. But I've had marathon runners	
4	are patients			
15	Q. Can the size of a bladder differ	15	drink three liters and it's okay because	
15 16	•		drink three liters and it's okay because they're out there running all the time.	
	Q. Can the size of a bladder differ	15	•	
16	Q. Can the size of a bladder differ in relation to the size of a woman, such	15 16	they're out there running all the time.	
16 17	Q. Can the size of a bladder differ in relation to the size of a woman, such that obese women tend to have larger	15 16 17	they're out there running all the time. So, again, that's where you	
16 17 18	Q. Can the size of a bladder differ in relation to the size of a woman, such that obese women tend to have larger bladders versus smaller-framed, normal	15 16 17 18	they're out there running all the time. So, again, that's where you have to look at the whole, big picture. But	
16 17 18 19	Q. Can the size of a bladder differ in relation to the size of a woman, such that obese women tend to have larger bladders versus smaller-framed, normal weight or underweight women?	15 16 17 18 19	they're out there running all the time. So, again, that's where you have to look at the whole, big picture. But on the average, large volume, greater than	
16 17 18 19 20	Q. Can the size of a bladder differ in relation to the size of a woman, such that obese women tend to have larger bladders versus smaller-framed, normal weight or underweight women? A. No, we know of no correlation	15 16 17 18 19 20	they're out there running all the time. So, again, that's where you have to look at the whole, big picture. But on the average, large volume, greater than say two liters a day is above the average.	
16 17 18 19 20 21	Q. Can the size of a bladder differ in relation to the size of a woman, such that obese women tend to have larger bladders versus smaller-framed, normal weight or underweight women? A. No, we know of no correlation that way.	15 16 17 18 19 20 21	they're out there running all the time. So, again, that's where you have to look at the whole, big picture. But on the average, large volume, greater than say two liters a day is above the average. That will lead to frequent urination because	
16 17 18 19 20 21 22	Q. Can the size of a bladder differ in relation to the size of a woman, such that obese women tend to have larger bladders versus smaller-framed, normal weight or underweight women? A. No, we know of no correlation that way. Q. And so if a woman drinks fluids	15 16 17 18 19 20 21 22	they're out there running all the time. So, again, that's where you have to look at the whole, big picture. But on the average, large volume, greater than say two liters a day is above the average. That will lead to frequent urination because the bladder will just fill up.	
16 17 18 19 20 21 22 23	Q. Can the size of a bladder differ in relation to the size of a woman, such that obese women tend to have larger bladders versus smaller-framed, normal weight or underweight women? A. No, we know of no correlation that way. Q. And so if a woman drinks fluids frequently throughout the day, there will be	15 16 17 18 19 20 21 22 23	they're out there running all the time. So, again, that's where you have to look at the whole, big picture. But on the average, large volume, greater than say two liters a day is above the average. That will lead to frequent urination because the bladder will just fill up. Q. So if a woman drinks more than	

		Page 474		Page 4	175
1	bladder will just fill up.		1	guess I don't understand what you mean by	
2	A. Well, no. I said I said more		2	factors that are involved.	
3	than two. Average consumption a day is one		3	Q. What are the things that lead to	
4	to 1.5 liters of fluid but that's also not		4	the acute onset of the need to void?	
5	counting food because about a third of your		5	A. Well, that indicates the	
6	urine can be from breakdown of food. So,		6	possibility of a bladder that is	
7	again, it gets very complicated.		7	malfunctioning, meaning it does spasms, but	
8	Q. So if a woman drinks more than		8	urgency can also be in the setting of a	
9	two liters a day, there will be more		9	bladder that does not empty out very well	
10	frequent urination because the bladder will		10	either.	
11	fill up?		11	And so bladder sensation is	
12	A. Unless they're exercising a lot		12	immensely complicated and those patterns can	
13	and then they'll burn the fluid off or if		13	then be learned in the spinal cord, which	
14	it's hot or they're in a humid environment.		14	actually the glial cells or astrocytes in	
15	So that's why you have to look at the whole		15	the spinal cord can learn behavior.	
16	totality.		16	Everything we do is learned,	
17	Q. Urinary urgency, how is that		17	whether it be typing on a computer or	
18	diagnosed?		18	reading, driving, that's learned, but then	
19	A. The most accurate way to diagnose		19	also a body can learn bad habits.	
20	urgency is by history, what the patient		20	Q. Can urinary urgency be a sporadic	
21	tells you.		21	symptom?	
22	Q. Does a history of what are the		22	A. If there is something in the	
23	factors that are involved in urinary		23	bladder that is an irritant, most likely	
24	urgency?		24	example in that situation would be something	
25	A. Factors that are involved? I		25	like a bladder infection, then you treat the	
23	A. Tactors that are involved: 1		23	ince a bladder infection, their you deat the	
		Page 476		Page 4	177
1	hladder infection, the bladder goes back	Page 476	1	Page 4	177
1	bladder infection, the bladder goes back	Page 476	1 2	Q. You're aware that she did have a	177
2	down to its baseline. So urgency of	Page 476	2	Q. You're aware that she did have a history of interstitial cystitis.	177
2	down to its baseline. So urgency of urination can occur in that. If it's a	Page 476	2 3	Q. You're aware that she did have a history of interstitial cystitis.A. Yes.	177
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2 3 4 5 6 7 8 9	down to its baseline. So urgency of urination can occur in that. If it's a neurologic or idiopathic, it's going to be the same, maybe precipitated by caffeine consumption, stress, nicotine. Q. Medications? A. Certain medications, cold medication, anything that is to clear the	Page 476	2 3 4 5 6 7 8 9	Q. You're aware that she did have a history of interstitial cystitis. A. Yes. Q. And that was before Prolift®; correct? A. Correct. Q. Can interstitial cystitis also lead to urinary frequency? A. Yes.	177
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		1		
	Page 478			Page 479
1	different pelvic neuroanatomy was involved	1	Q. And you comment on the pain of	
2	because, again, you have the sympathetic and	2	pelvic floor myalgia with Mrs. Wicker;	
3	parasympathetic nervous system right in that	3	correct?	
4	area. They do different things.	4	A. Yes.	
5	And also you have with the	5	Q. You saw that Dr. Weber also	
6	trocars of the Prolift® with the potential	6	opined on that subject?	
7	for pudendal nerve issues, too. And that	7	A. Yes.	
8	controls a completely different aspect of	8	Q. You saw that Dr. Margolis also	
9	urination and sensation.	9	opined on that subject?	
10	Q. In your report did you	10	A. Yes.	
11	specifically opine that the trocars from the	11	Q. Do you believe that something	
12	Prolift® caused some type of injury to	12	different should have been done by	
13	Mrs. Wicker?	13	Mrs. Wicker's physicians to treat her pain?	
14	A. Well, no. I say the Prolift®	14	A. No. I think they're they're	
15	surgery. That's all-encompassing so that	15	doing everything they can.	
16	could include or it does not exclude trocar	16	Q. Do you believe that something	
17	use.	17	different should have been done with regard	
18	Q. Did the trocar use in	18	to Mrs. Wicker's pelvic floor myalgia?	
19	Mrs. Wicker's surgery cause her any of these	19	A. No. I think they're doing	
20	symptoms or injuries that you have set forth	20	everything they can. And according to	
21	in your report?	21	Dr. Raz's deposition, which I watched the	
22	 A. I can't say they did or did not. 	22	video on, he would he's doing exactly	
23	I said they could be a contributing factor	23	what I would have done.	
24	but I've not I have not opined that they	24	Q. You saw Dr. Raz performed a	
25	did or did not.	25	prolapse surgery on Mrs. Wicker, then?	
	Page 480			Page 481
1	A. No. I saw the his deposition,	1	Q. Are you aware of any randomized,	rage 401
2	his video deposition. I didn't see his	2	controlled trials looking at that Raz	
3	surgery.	3	surgery of interlocking sutures	
4	Q. Didn't he testify about that	4	A. No.	
5	surgery he performed in Mrs. Wicker for	5	Q to treat prolapse?	
6	prolapse?	6	A. No.	
7	A. Yeah. But you say you saw	7	Q. For Mrs. Wicker, is it possible	
8	doctor, it's Raz, R-A-Z, not Rose, you saw	8	that her bladder pain will at some point go	
9	Dr. Rose Dr. Raz performed a prolapse	9	away?	
10	surgery.	10	A. I I hope so. I have no idea.	
11	Oh, I see. I thought you said	11	Q. You cannot say for certain	
12	did I actually visualize the surgery. I	12	whether her bladder pain will go away or	
13	misunderstood your question.	13	not.	
14	Yes, I saw that he performed a	14	A. No. No. These mesh	
15			complications are too soon. We don't know	
	prolapse surgery. Yes. That's my fault.	15		
16	prolapse surgery. Yes. That's my fault. Q. And in it Dr. Raz described it as	16	long term.	
16 17	, , , ,			
	Q. And in it Dr. Raz described it as	16	long term.	
17	Q. And in it Dr. Raz described it as a procedure by which he wove different sutures to form a net.	16 17	long term. Q. Is it possible that Mrs. Wicker's	
17 18 19	Q. And in it Dr. Raz described it as a procedure by which he wove different sutures to form a net. A. Yeah. He used, as I recall,	16 17 18	long term. Q. Is it possible that Mrs. Wicker's urinary frequency will go away? A. It is possible.	
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		Page 482			Page 483
1	A. Again, that depends upon the		1	to be repeated on the average every four to	- 1
2	etiology. If it's idiopathic, usually no.		2	six months.	- 1
3	If there's some insult that can be corrected		3	If that fails, interstim, which	- 1
4	and there's been no damage to the		4	is or peripheral nerve stimulation of	- 1
5	neuroanatomy, then yes.		5	some sort.	- 1
6	Q. How is urinary frequency treated,		6	If that fails and the patient	- 1
			7	•	- 1
7	non-idiopathic urinary frequency?			is miserable, bladder augmentation surgery,	- 1
8	A. Trying to relieve the underlying		8	which is a major step, which is not done	- 1
9	insult or etiology. If you're not able to		9	very often anymore.	- 1
10	treat the underlying etiology, then you can		10	Q. Do you know if Mrs. Wicker was	- 1
11	try medications like well, you can do		11	compliant with recommendations for her to	- 1
12	time voiding, meaning the patient goes to		12	use vaginal estrogen?	- 1
13	the bathroom on a schedule.		13	A. I don't know.	- 1
14	You can try avoidance of		14	Q. Do you know if Mrs. Gross was	- 1
15	dietary irritants, big three, caffeine,		15	compliant with recommendations for her to	- 1
16	nicotine and then stress is not a dietary		16	use vaginal estrogen?	- 1
17	irritant but it's an irritant.		17	A. I don't know. I don't recall	- 1
18	Pelvic floor retraining,		18	reading that in the or hearing it in the	- 1
19	bladder retraining. At times, vaginal		19	deposition.	- 1
20	estrogen replacement. Then if you're into		20	Q. What type of medications can one	- 1
21	the medication, then it's the		21	take for urinary urgency?	- 1
22			22		- 1
	anticholinergic medications, which there's a			A. It's the same thing as frequency.	- 1
23	whole host of those.		23	It's the anticholinergics, which is a large	- 1
24	If that fails, then you have		24	family of medication. I shouldn't say a	- 1
25	Botox injections to the bladder, which need		25	large family. There's six or seven of them.	- 1
		Page 484			Page 485
1	Q. Can you tell me the names of just	Page 484	1	A. If the underlying irritation,	Page 485
2	a couple so I	Page 484	2	inflammation gets better, there's the	Page 485
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	Page 4	36		Page 487
1	obstruction; correct?	1	Anterior prolapse can cause	
2	A. That is correct.	2	urinary urgency, frequency, poor emptying,	
3	Q. And once that mechanical	3	those things; however, it is relatively rare	
4	obstruction is removed from the equation,	4		
5	then the voiding dysfunction can return to	5		
6	strike that. Start all over again.	6	- •	
7	And once that mechanical	7	- , , , ,	
8	obstruction is removed from the equation,	8		
9	voiding conditions can normalize; correct?	9		
10	A. There is there is a chance of	10	•	
11	it, yes.	11	-	
12	Q. Prolapse can lead to voiding	12		
13	dysfunction; correct?	13		
14	A. Yes.	14	, ,	
15	Q. Is it a certain type of prolapse	15	5 , ,	
16	or any prolapse, be it anterior, posterior,	16		
17	apical?	17		
18	A. It would be specifically related	18	, , , , , , , , , , , , , , , , , , , ,	
19	to the bladder. So posterior prolapse and	19	• • • • • • • • • • • • • • • • • • • •	
20	rectum is unlikely to be causing much in the	20		
21	way of voiding dysfunction.	21	·	
22	Apical prolapse also is	22	- · · · · · · · · · · · · · · · · · · ·	
23	unlikely to. It possibly could but, again,	23	•	
24	if it doesn't involve the bladder, it should	24		
25	not impede much.	25	• •	
23	not impede mach.	23	MIN. ANDLINSON. Objection.	
	Page 4	38		Page 489
1	Page 4 Except anything I may ask him.	38 1	consistent with injury or irritation or	Page 489
1 2	Except anything I may ask him.	_	, , , , , , , , , , , , , , , , , , ,	Page 489
2	Except anything I may ask him. MR. SNELL: Let's go off the	1 2	insult to the pudendals and the sympathetic	Page 489
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2 3 4	Except anything I may ask him. MR. SNELL: Let's go off the record. Let me just check and see if I have anything else.	1 2 3 4	insult to the pudendals and the sympathetic and parasympathetic. Q. So you have an opinion that her	Page 489
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				1
	Page 490			Page 491
1	filling of the bladder neck, filling of the	1	Pudendal nerve irritation can	
2	bladder. If you have irritation to those	2	present with urinary frequency, slowed	
3	nerves, that's going to impair the filling	3	urinary stream due to effects of the	
4	phase. So subsequently you can get	4	external sphincter muscle, and so that can	
5	frequency, you can get urgency because these	5	cause those symptoms. What I can say is	
6	nervous systems, all three, work in concert	6	it's consistent with. I cannot prove.	
7	and they all have to be finely tuned, and if	7	BY MR. SNELL:	
8	you disrupt one without affecting the other,	8	Q. Can pelvic can urinary	
9	that will throw everything off.	9	dysfunction be a result of pelvic floor	
10	And so based upon the	10	spasms?	
11	symptomatology, I can go down the nervous	11	A. Well, pelvic floor spasms aren't	
12	system of what may be responsible for that.	12	aren't a diagnosis. I think that's along	
13	Q. Well, what I want to understand	13	the lines of pelvic floor myalgia. And then	
14	is, do you have an opinion to a reasonable	14	yes. Your question was dysfunction, yes.	
15	degree of medical certainty that	15	To answer your question, yes,	
16	Mrs. Wicker's pudendal nerves were injured,	16	urinary dysfunction can be a result of	
17	not that they may have been injured but that	17	pelvic floor myalgia, as I call it, not	
18	they actually were injured?	18	spasms.	
19	MR. ANDERSON: Objection.	19	Q. Urinary dysfunction can be a	
20	Go ahead.	20	result of pelvic floor myalgia; correct?	
21	THE WITNESS: I cannot say	21	A. Yes.	
22	since I was not in the surgery that a trocar	22	Q. What is the difference, Doctor,	
23	or mesh were put through those nerves. I	23	between pelvic floor myalgia and pelvic	
24	can't say that. All I can go off of is the	24	floor spasms?	
25	symptomatology following surgery.	25	A. Well, spasms is kind of a	
	Page 492			Page 493
1		1	A. Yes.	Page 493
1 2	Page 492 description of of literally a muscle spasm. Myalgia is indicating pain or	1 2	A. Yes. Q. They can obtain information	Page 493
	description of of literally a muscle		Q. They can obtain information	Page 493
2	description of of literally a muscle spasm. Myalgia is indicating pain or	2		
2	description of of literally a muscle spasm. Myalgia is indicating pain or tightening of the pelvic floor. You're	2 3	Q. They can obtain information relevant to a surgery they may perform by	
2 3 4	description of of literally a muscle spasm. Myalgia is indicating pain or tightening of the pelvic floor. You're technically correct, it's just not the terms	2 3 4	Q. They can obtain information relevant to a surgery they may perform by attending conferences such as those you have	
2 3 4 5	description of of literally a muscle spasm. Myalgia is indicating pain or tightening of the pelvic floor. You're technically correct, it's just not the terms that we use in the voiding dysfunction	2 3 4 5	Q. They can obtain information relevant to a surgery they may perform by attending conferences such as those you have attended?	
2 3 4 5 6	description of of literally a muscle spasm. Myalgia is indicating pain or tightening of the pelvic floor. You're technically correct, it's just not the terms that we use in the voiding dysfunction world.	2 3 4 5 6	Q. They can obtain information relevant to a surgery they may perform by attending conferences such as those you have attended? A. Yes.	
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1	Journal of Urology, Urology, and then		1	surgery; correct?	
2	Journal of Neurourology and Urodynamics, I		2	A. Yes.	
3	think, but now with the Internet we have		3	Q. The first da Vinci robot surgery	
4	access to PubMed, which actually is better		4	you performed was in approximately 2001 or	
5	because now we get gynecology and OB. It's		5	2002; correct?	
6	easy access.		6	A. Correct.	
7	Q. When did you obtain access to		7	Q. And you performed that with your	
8	PubMed at the Mayo Clinic?		8	colleague, Dr. George Chow; correct?	
9	A. I don't know when it became		9	A. Correct.	
10	available. I mean, it would have been		10	Q. And he is actually the one who is	
11	2000-something. I'd have to go back and		11	fellowship trained in robotics; correct?	
12	look for it. I don't know. We always had a		12	A. Correct.	
13	Medline search or something like that.		13	Q. He is actually the one who drives	
14	Q. So if you wanted to do research		14	the robot; correct?	
15	on a medical issue when you were at Mayo		15	A. Yes.	
16	Clinic, you could perform that type of		16	Q. Do you feel comfortable driving	
17	literature search?		17	the robot during a robotic laparoscopic	
18	A. Correct.		18	sacrocolpopexy?	
19	Q. Surgeons obtain information		19	A. No.	
20	relevant to surgery from their actual		20	Q. Do you agree that it takes a high	
21	clinical experience with that surgery as		21	degree of training to perform robotic	
22	well; correct?		22	laparoscopic sacrocolpopexy?	
23	A. That is correct.		23	A. It takes experience above and	
24	Q. And that is a very important		24	beyond just a normal surgeon.	
25	source of information with regard to a		25	Q. Are you credentialled to perform	
				Q. 7.10 you dicaditation to perform	
	Pag	je 496			Page 497
1	the da Vinci robotic laparoscopic		1	A. I don't know the answer to that	
2	sacrocolpopexy?		2	because Dr. Chow is fellowship trained in	
3	A. No.		3	both so there was never an issue as far as	
4	Q. Does Mayo Clinic have a specific		4	credentialling and nobody at Mayo that I	
5	credentialling program for a surgeon who		5	know of does a pure laparoscopic	
6	would wish to do the da Vinci robotic		6	sacrocolpopexy. That's a difficult	
7	laparoscopic sacrocolpopexy?		7	procedure.	
8	A. No. As long as you've been able		8	Q. A laparoscopic sacrocolpopexy you	
9	to show proficiency in robotic procedure,		9	would agree is a difficult procedure?	
10	you would be able to do it. But you have to		10	A. Yes.	
11	be able to show proficiency in robotics and		11	MR. SNELL: That's all the	
112	have to I mean, you're going to have to		12	questions I have for right now.	
12	nave to I mean, you're going to have to				
13	be in the urogynecology or urology		13	(Whereupon the deposition	
	, , , ,		13 14	(Whereupon the deposition concluded at 3:12 p.m.)	
13	be in the urogynecology or urology			· · · · · · · · · · · · · · · · · · ·	
13 14	be in the urogynecology or urology department to do it. A general surgeon is		14	concluded at 3:12 p.m.)	
13 14 15	be in the urogynecology or urology department to do it. A general surgeon is not going to do it.		14 15	concluded at 3:12 p.m.)	
13 14 15 16	be in the urogynecology or urology department to do it. A general surgeon is not going to do it. Q. If you wanted to perform a		14 15 16	concluded at 3:12 p.m.)	
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		Page 498					Page 499
1 2	CERTIFICATE		1	DACE		LAWYER'S NOTES	
3 4 duly swo 5 record of 6 7 completic DANIEL 1 8 to read a 9 10 11 12 13 14 15 16 17 18 this trans 19 reproduc 20 unless un 21	I HEREBY CERTIFY that the witness was rn by me and that the deposition is a true the testimony given by the witness. It was not requested before on of the deposition that the witness, STEVEN ELLIOTT, M.D., have the opportunity and sign the deposition transcript. ROSEMARY LOCKLEAR REGISTERED PROFESSIONAL REPORTER CERTIFIED COURT REPORTER (NJ) 30XI00171000 CERTIFIED REALTIME REPORTER NOTARY PUBLIC Dated: 12/10/12 (The foregoing certification of script does not apply to any tion of the same by any means, ander the direct control and/or on of the certifying reporter.)		2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23		LINE		
24 25			24 25				